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Brambilla

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(54) **VENTILATION MASK WITH INTEGRATED PILOTED EXHALATION VALVE**

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See application file for complete search history.

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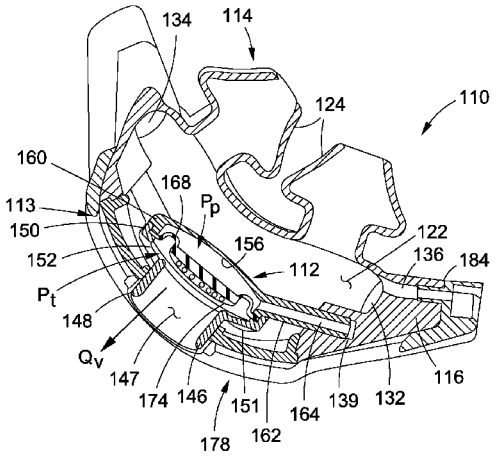
(57) **ABSTRACT**

A mask for achieving positive pressure mechanical ventilation (inclusive of CPAP, ventilator support, critical care ventilation, emergency applications), and a method for a operating a ventilation system including such mask. The mask includes a piloted exhalation valve that is used to achieve the target pressures/flows to the patient. The pilot for the valve may be pneumatic and driven from the gas supply tubing from the ventilator. The pilot may also be a preset pressure derived in the mask, a separate pneumatic line from the ventilator, or an electro-mechanical control. The mask of the present invention may further include a heat and moisture exchanger (HME) which is integrated therein.

20 Claims, 14 Drawing Sheets



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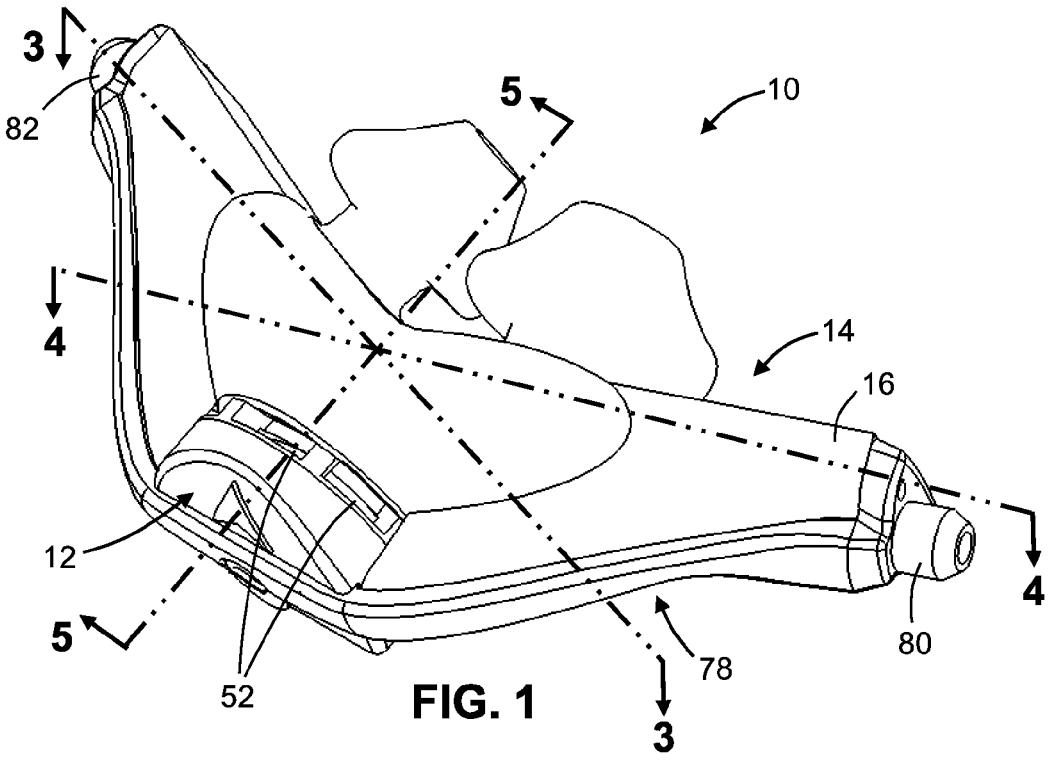
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FIG. 1

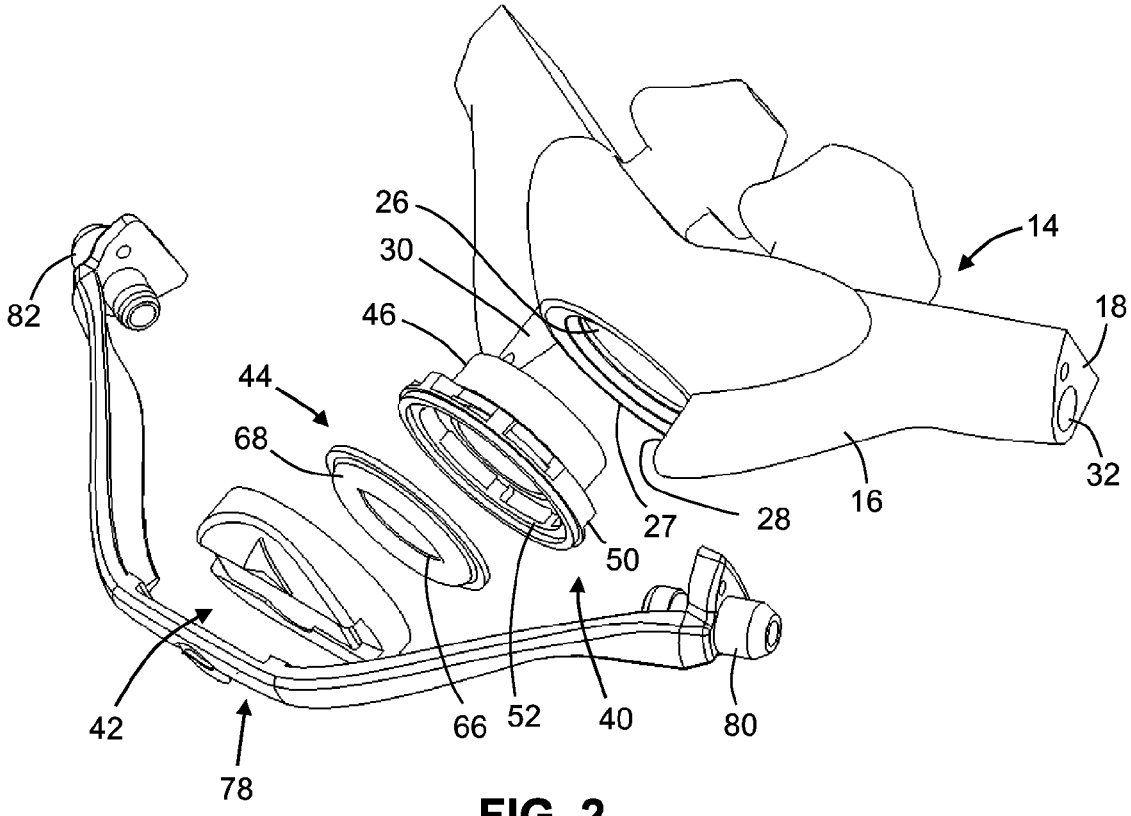
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FIG. 2

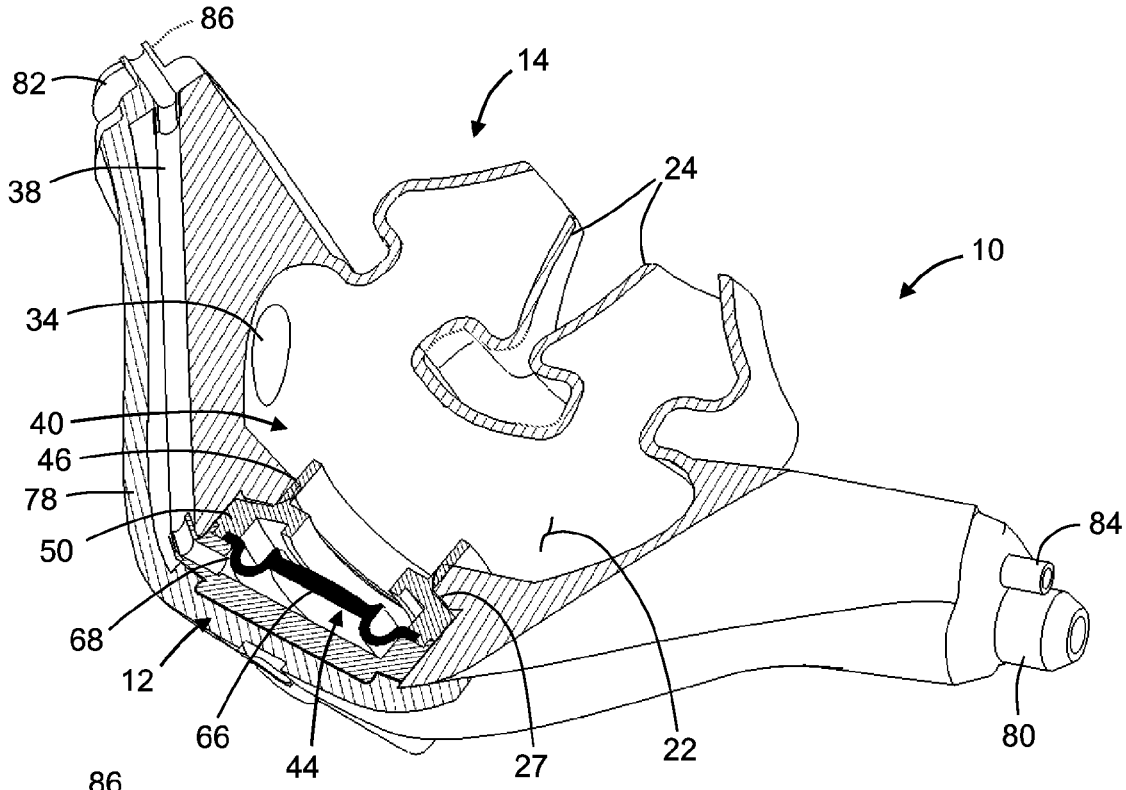
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FIG. 3

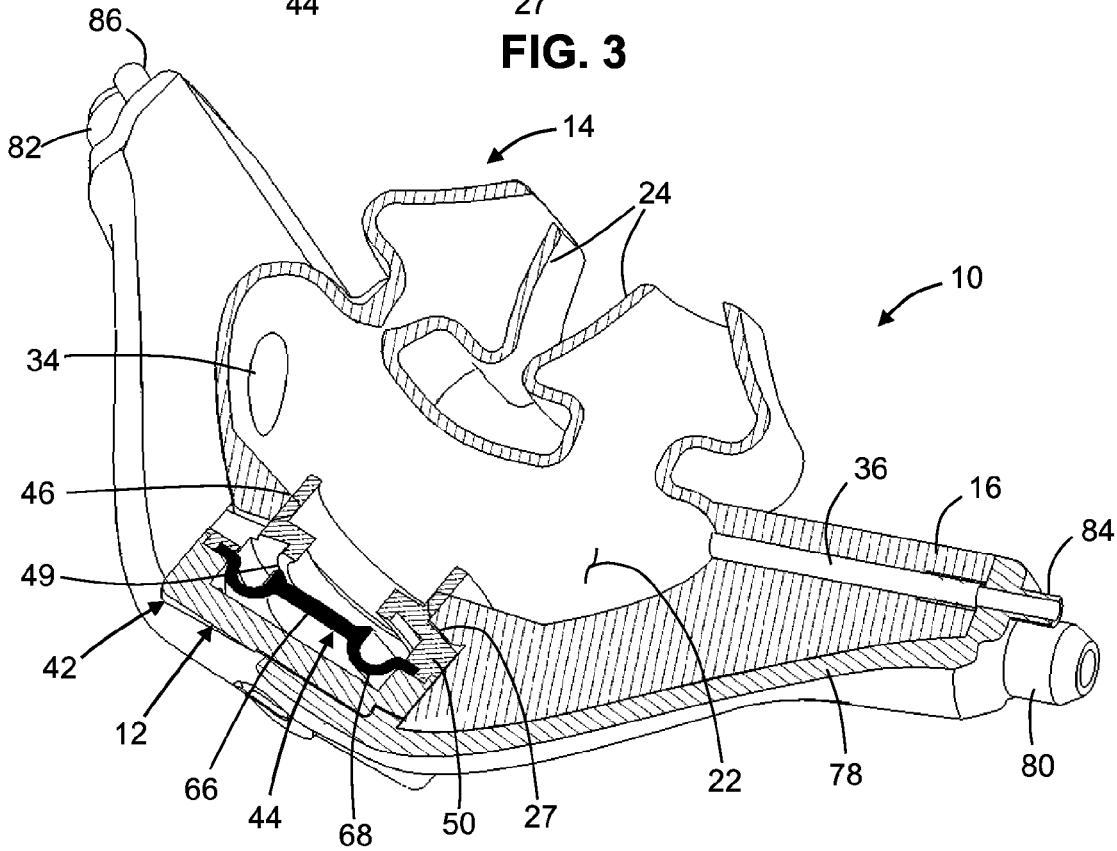
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FIG. 4

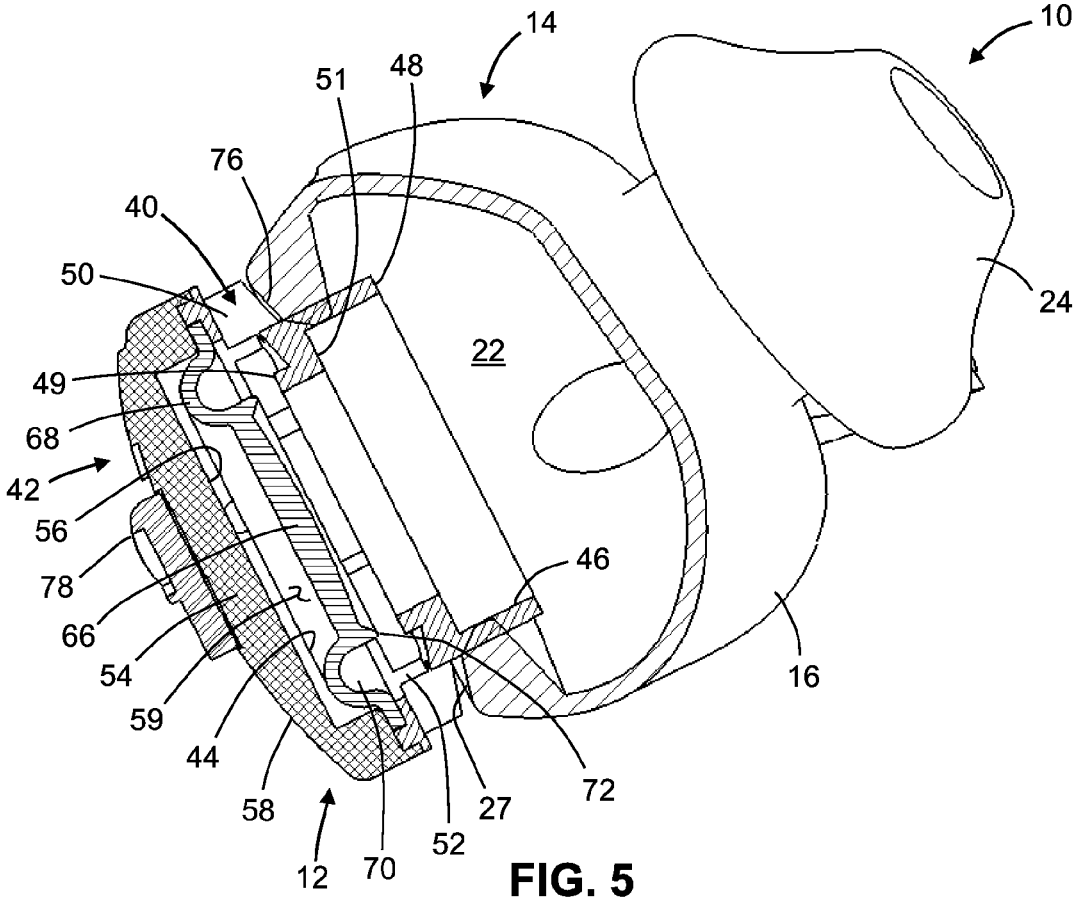
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FIG. 5

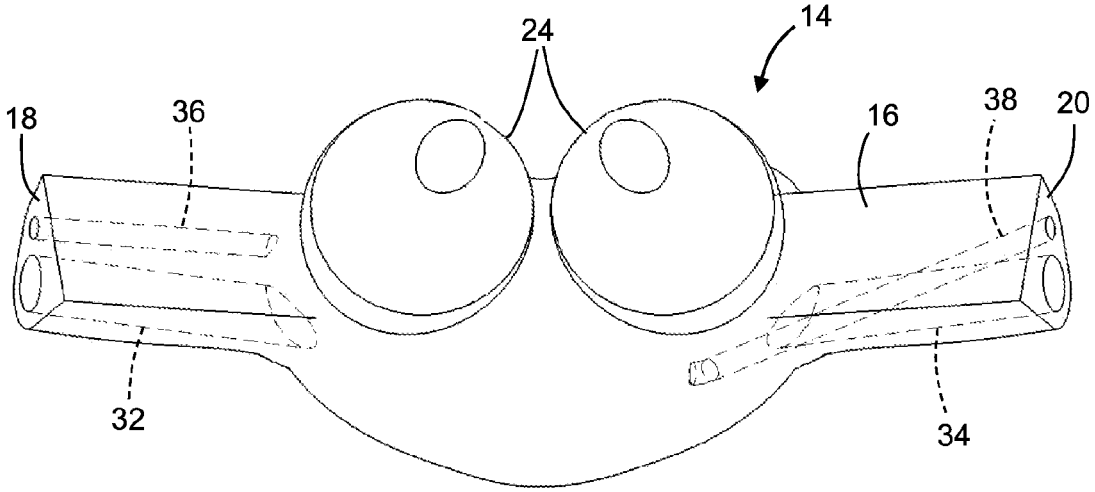
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FIG. 6

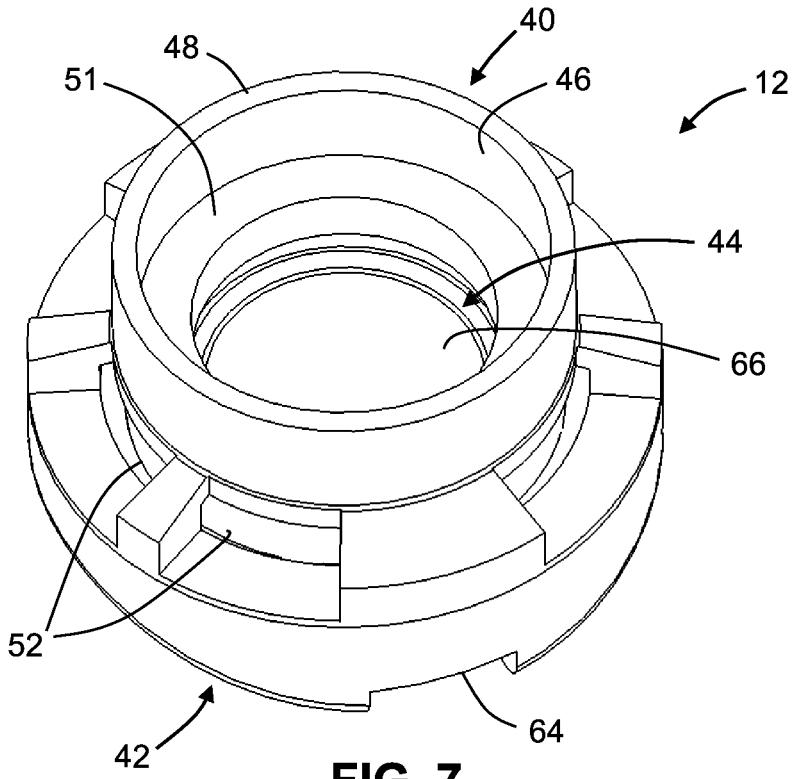
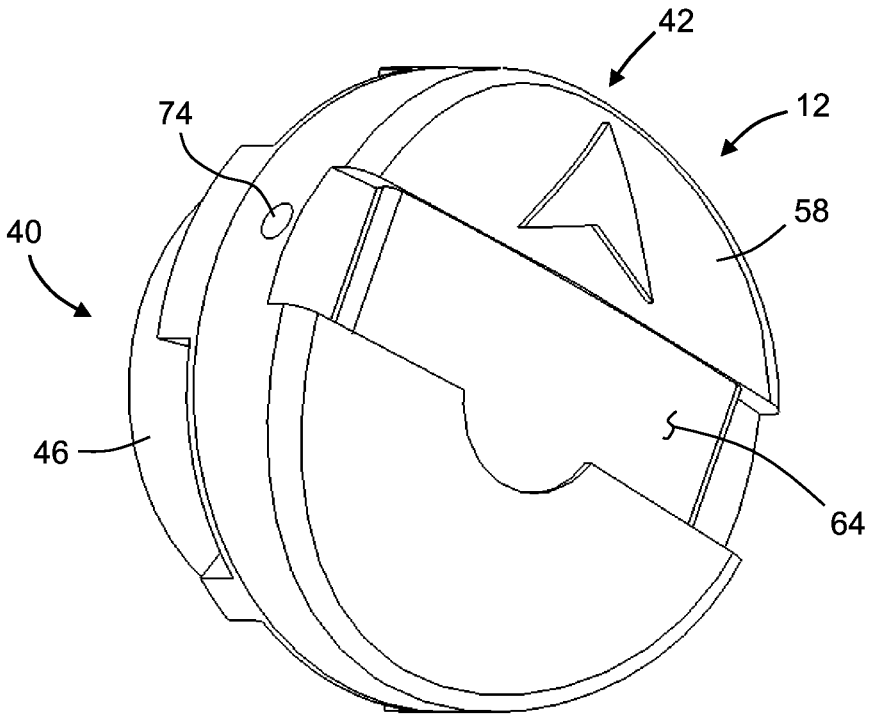


FIG. 7



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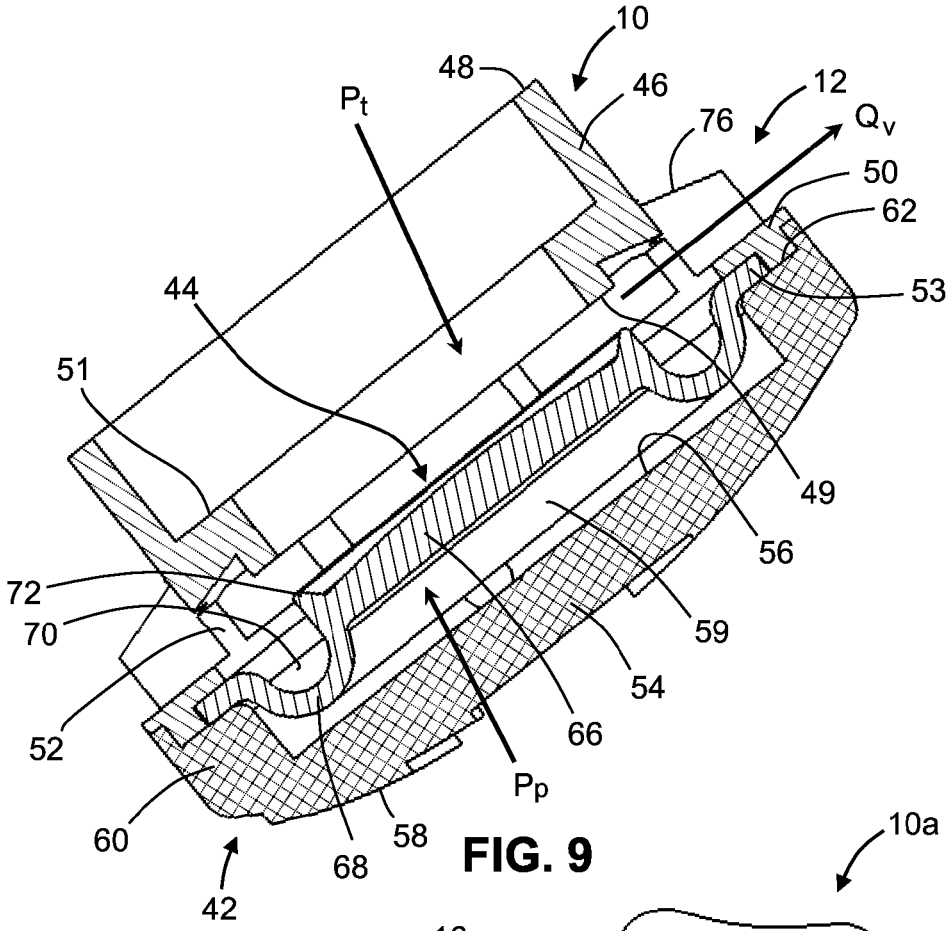
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FIG. 9

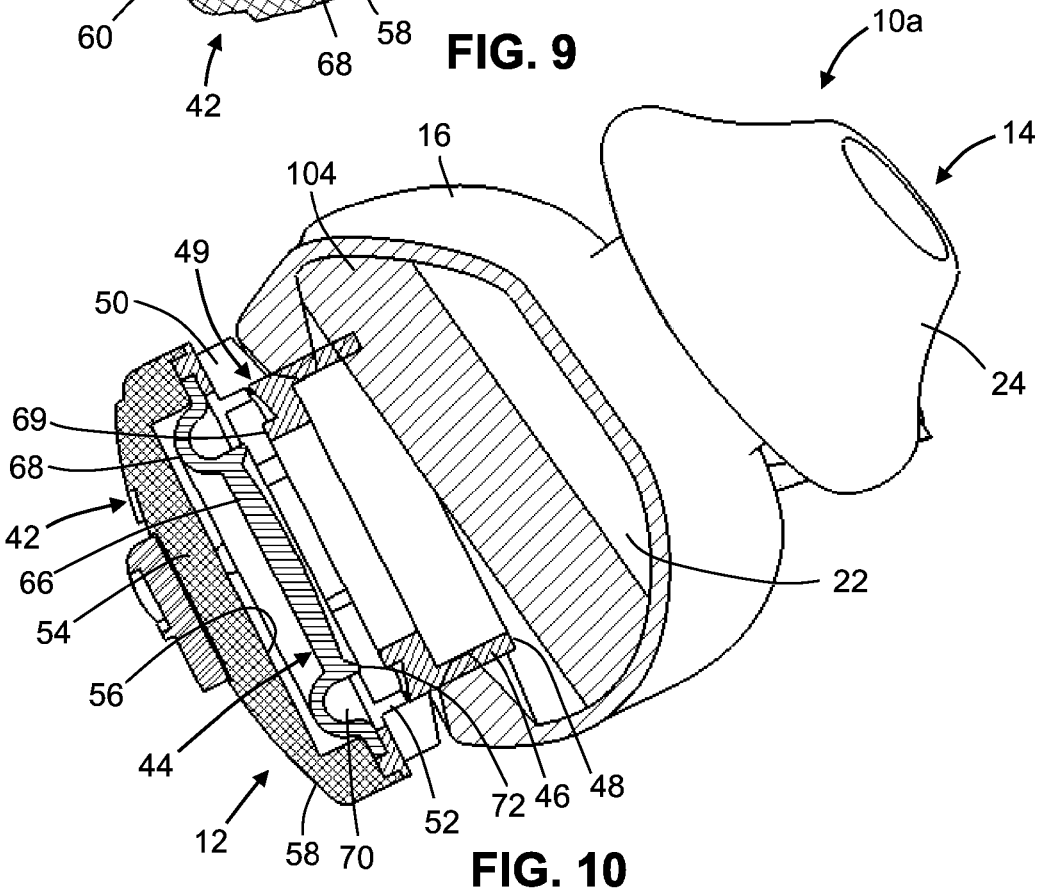
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FIG. 10

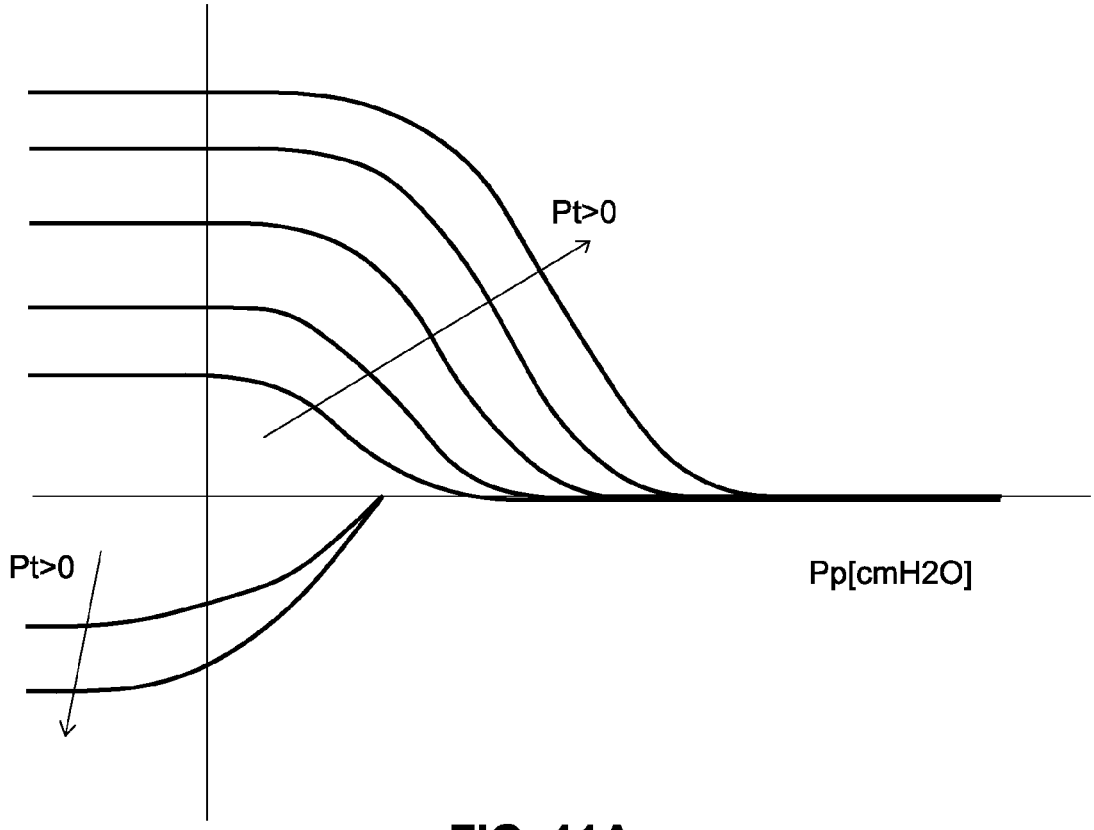

FIG. 11A

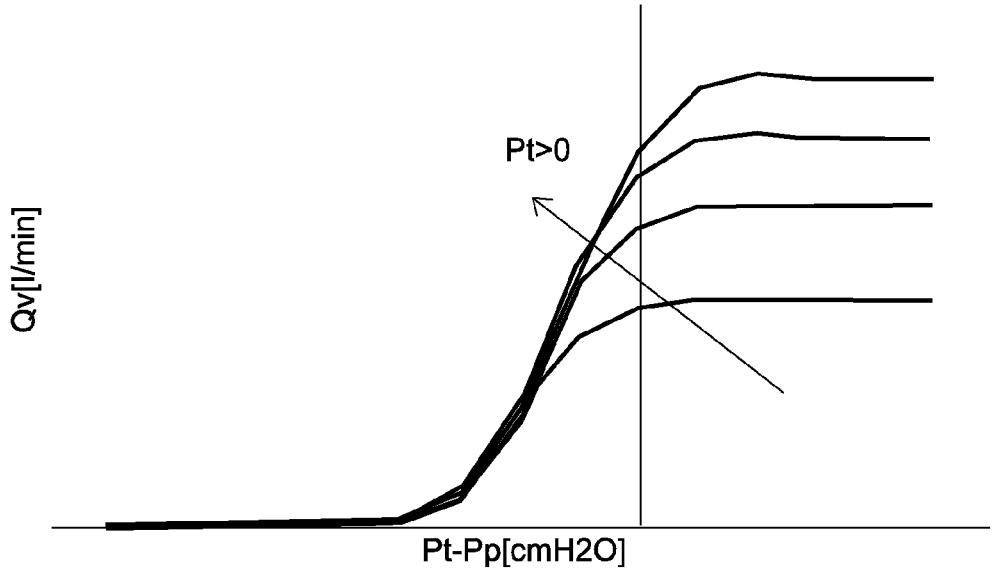

FIG. 11B

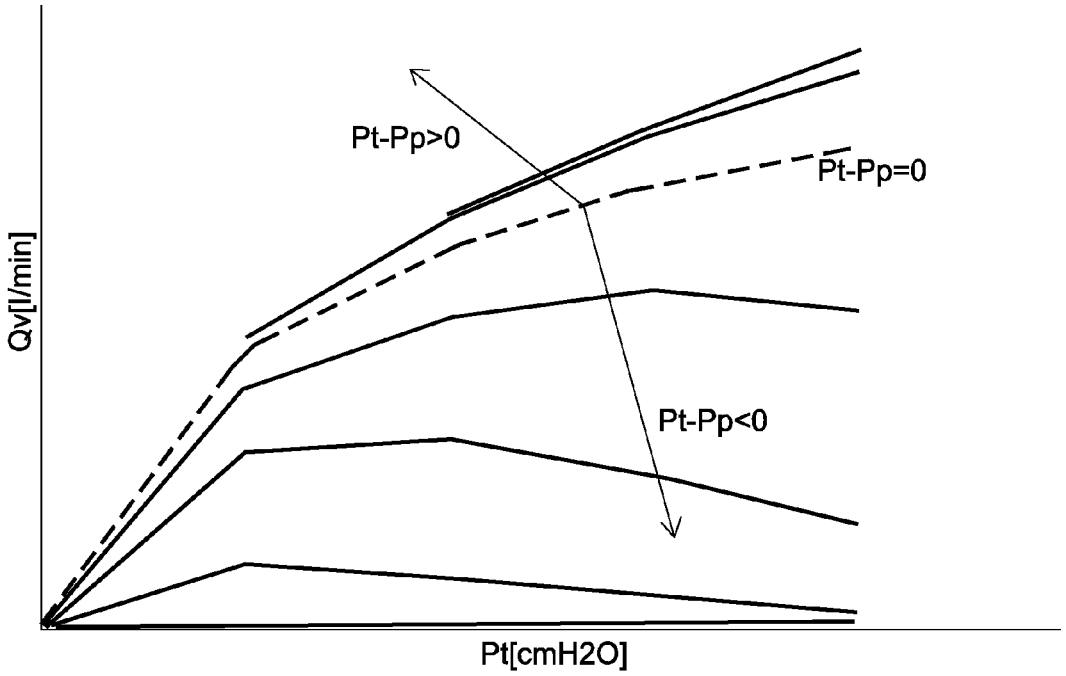

FIG. 11C

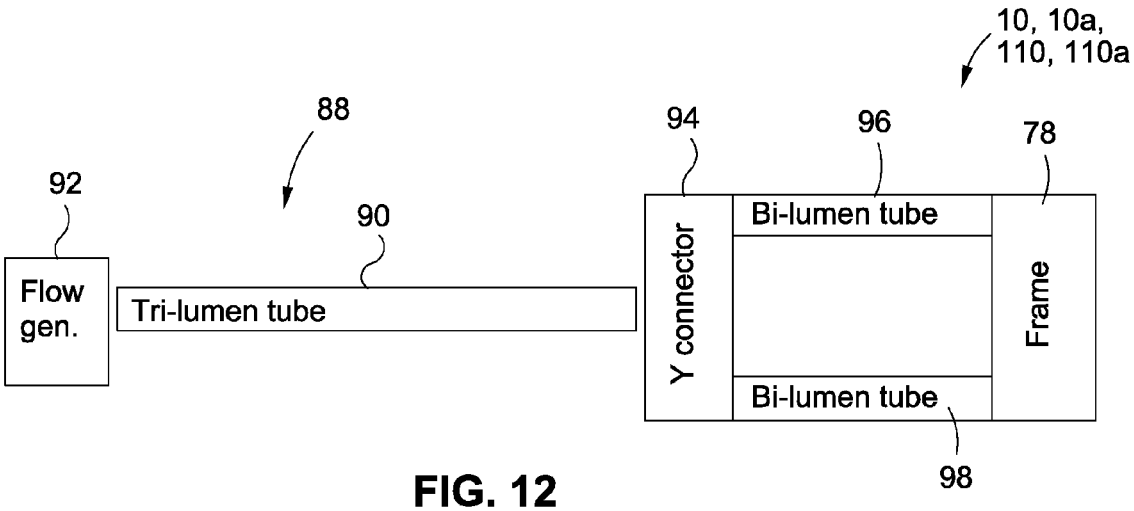

FIG. 12

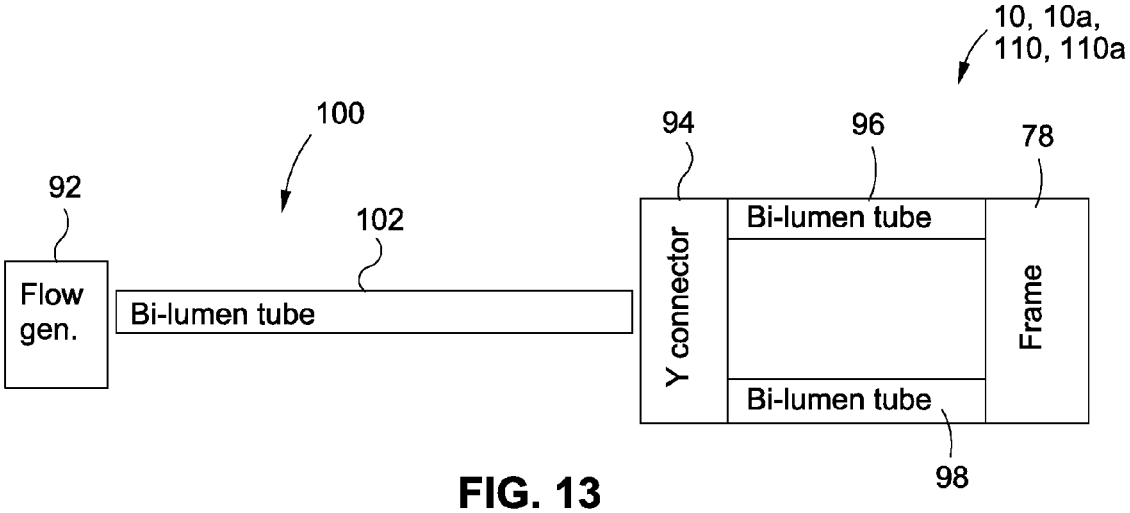
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FIG. 13

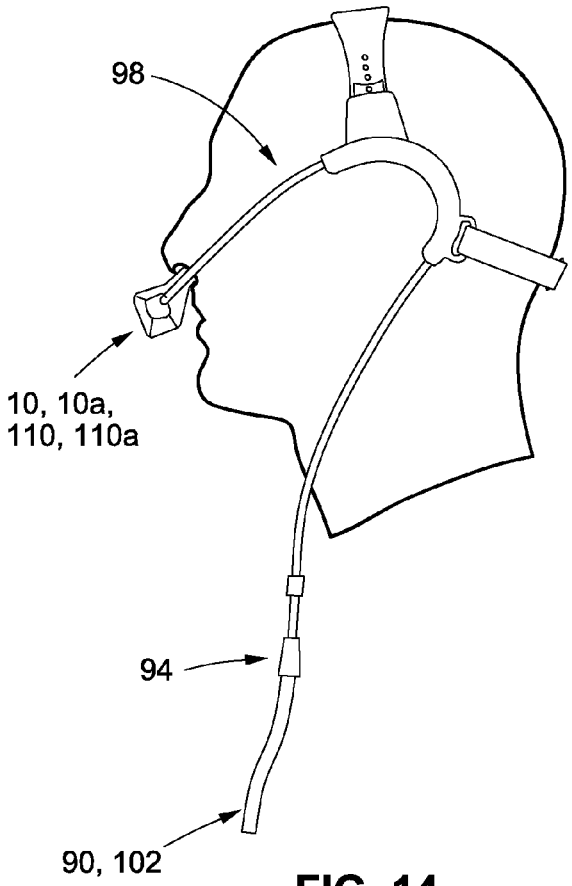
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FIG. 14

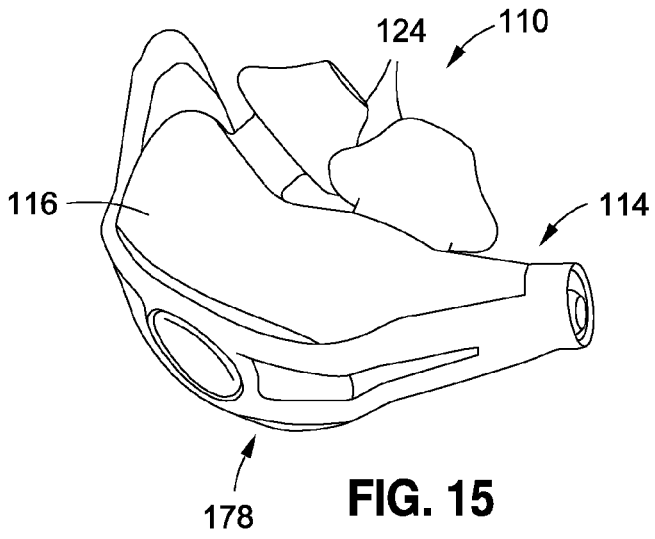
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FIG. 15

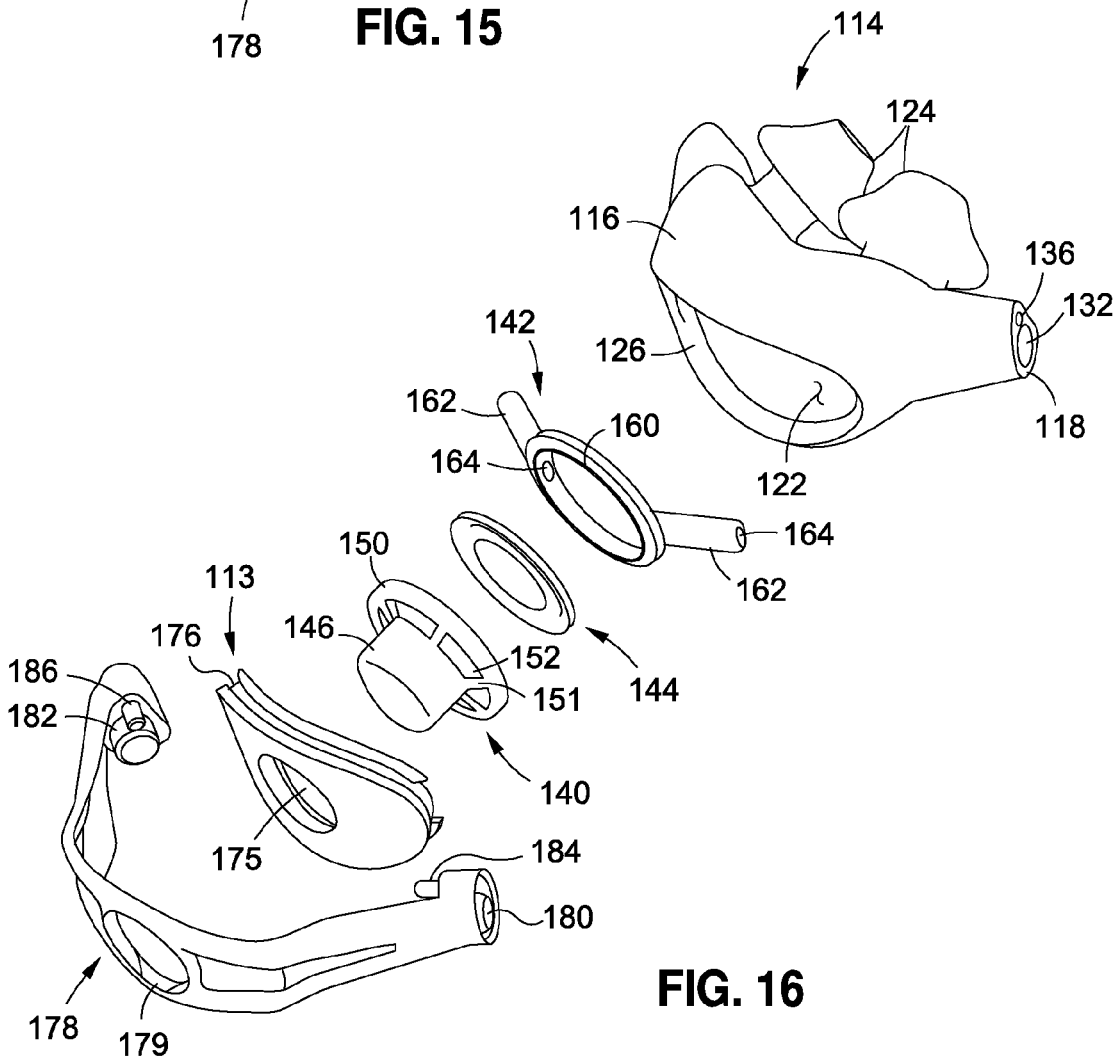
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FIG. 16

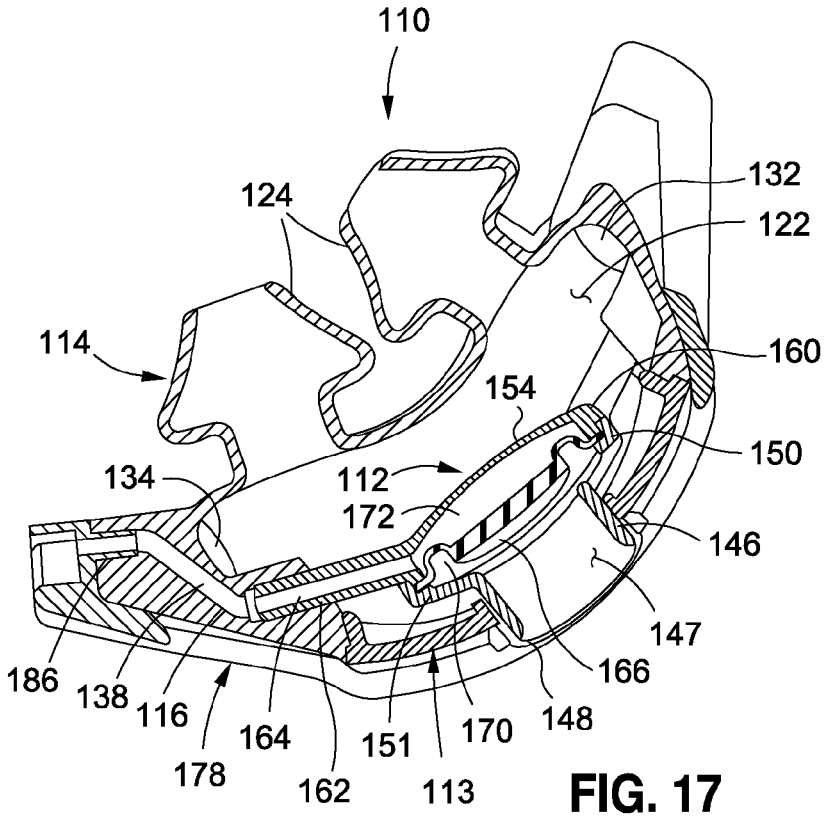
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FIG. 17

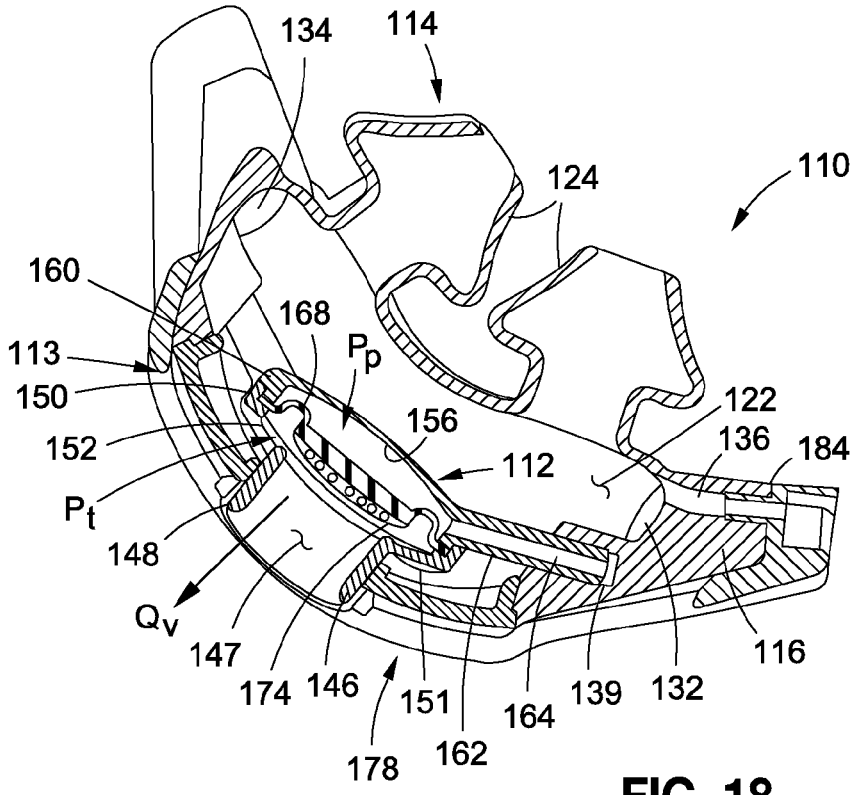
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FIG. 18

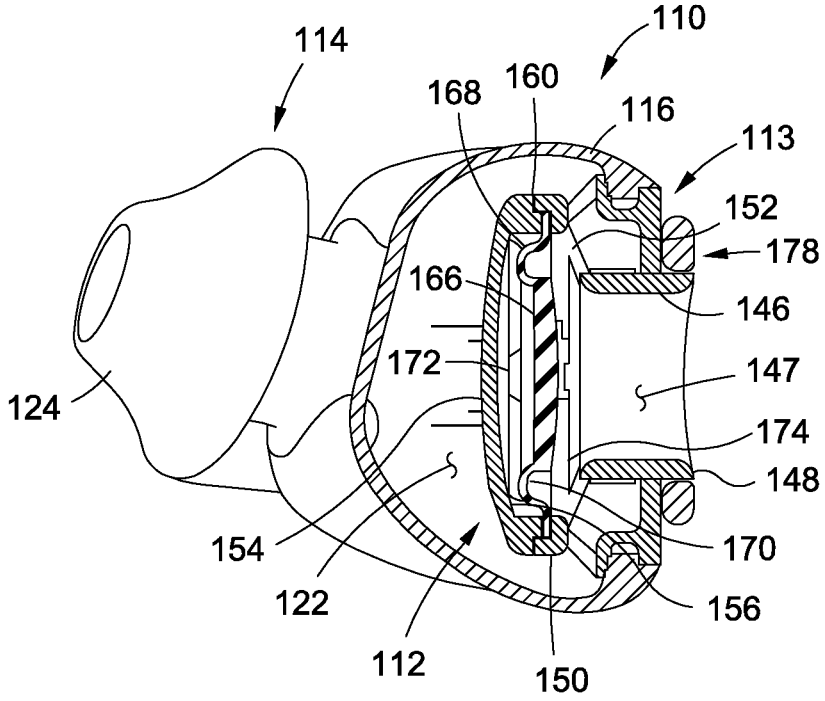
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FIG. 19

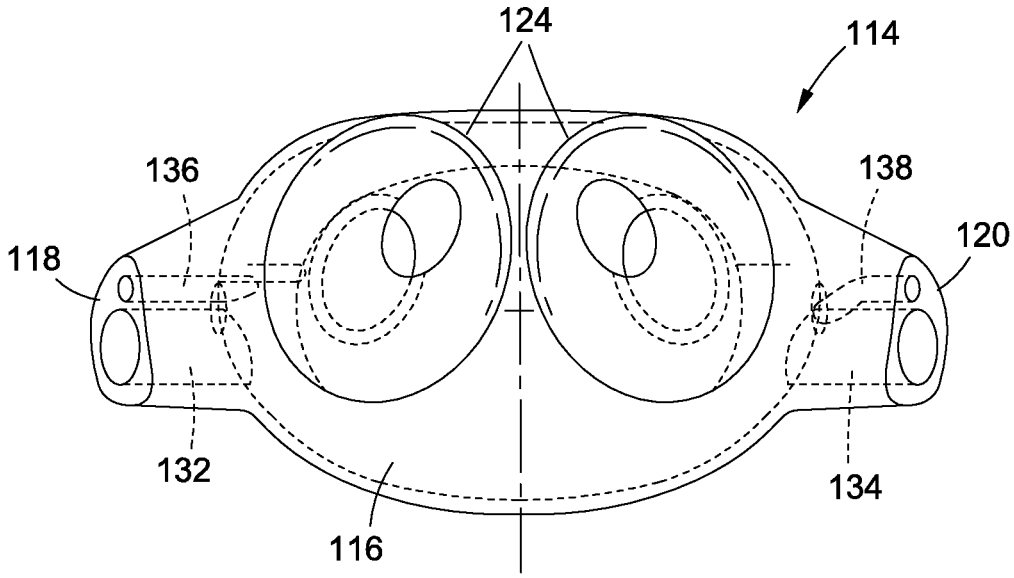
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FIG. 20

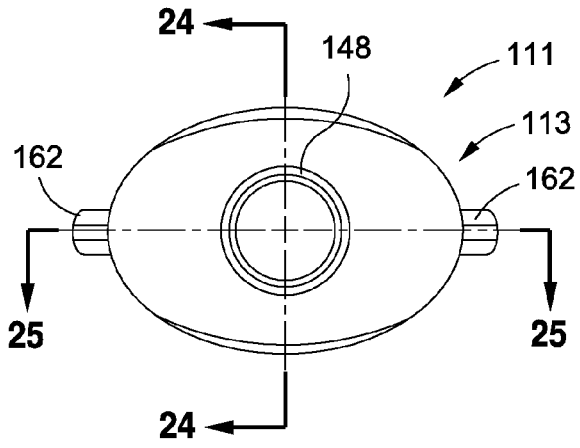

FIG. 21

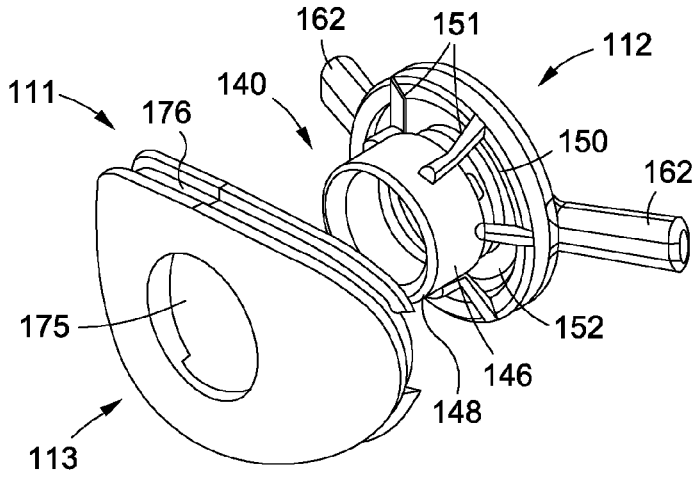

FIG. 22

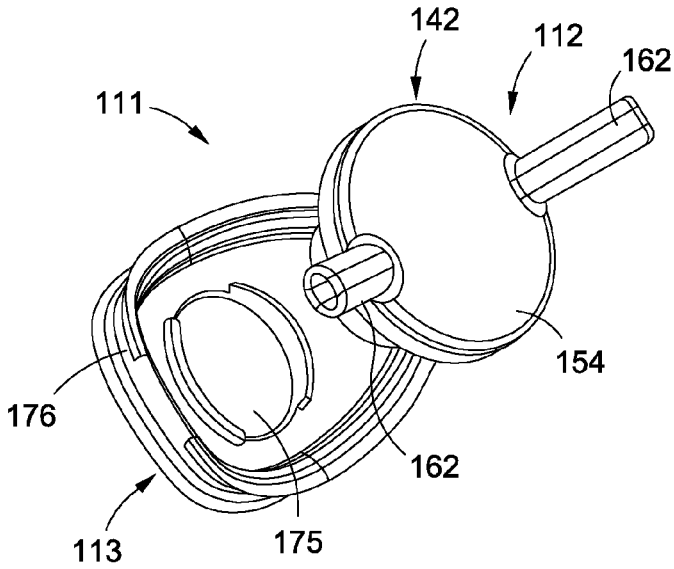

FIG. 23

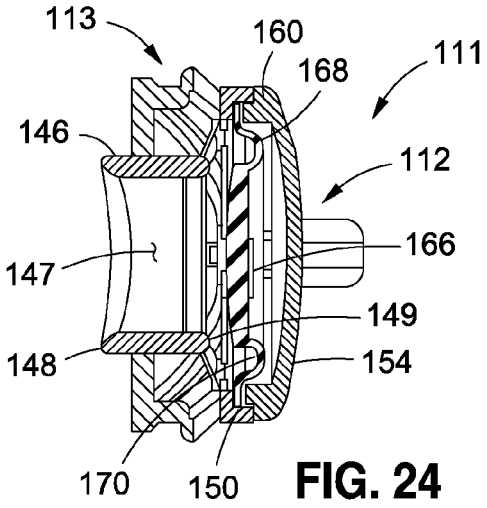

FIG. 24

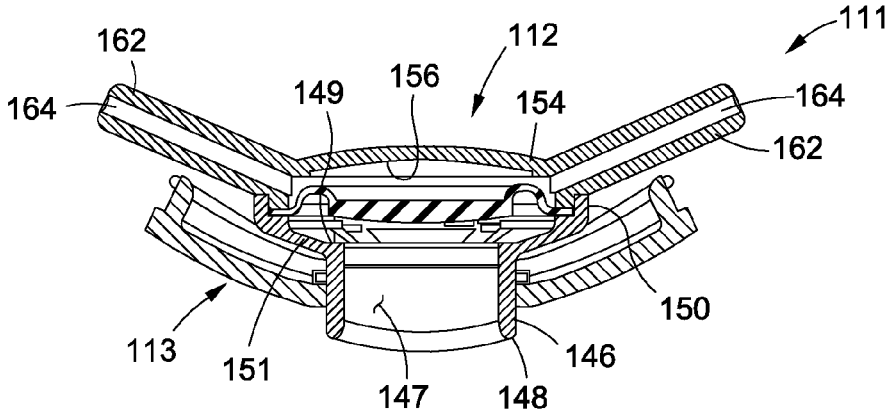

FIG. 25

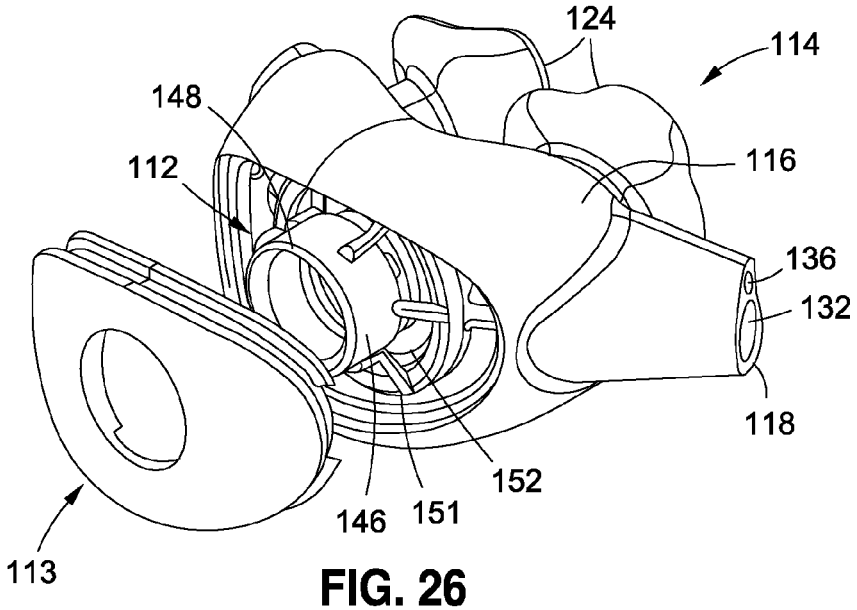

FIG. 26

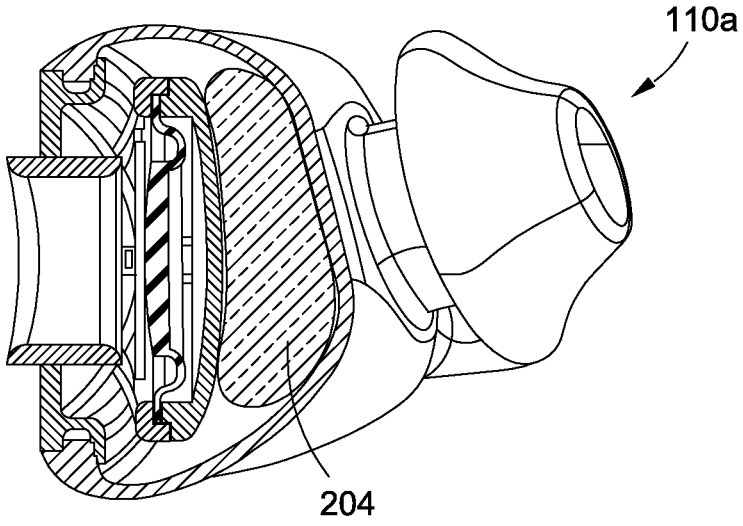

FIG. 27

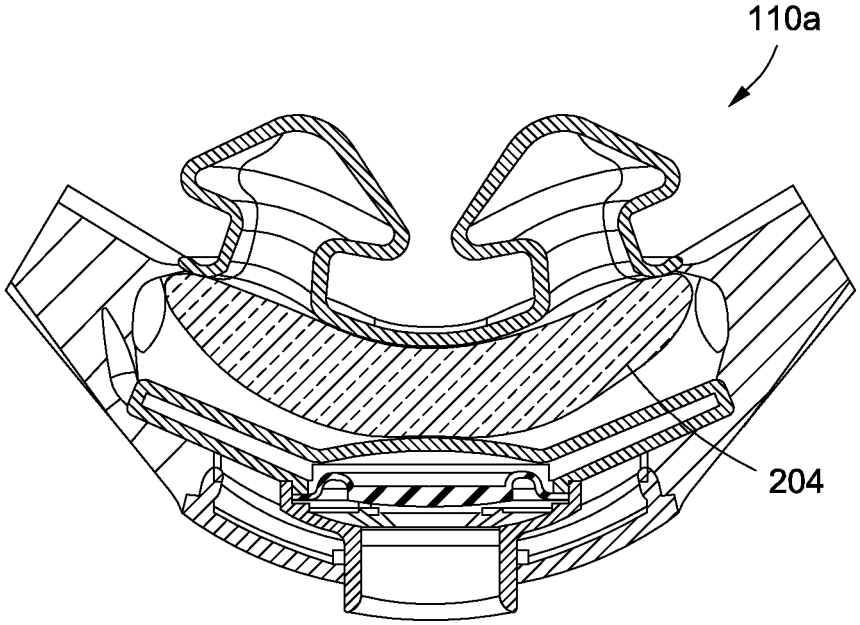

FIG. 28

VENTILATION MASK WITH INTEGRATED PILOTED EXHALATION VALVE

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation-in-part of U.S. application Ser. No. 13/411,348 entitled VENTILATION MASK WITH INTEGRATED PILOTED EXHALATION VALVE filed Mar. 2, 2012, which claims priority to U.S. Provisional Patent Application Ser. No. 61/499,950 entitled VENTILATION MASK WITH INTEGRATED PILOTED EXHALATION VALVE filed Jun. 22, 2011, and U.S. Provisional Patent Application Ser. No. 61/512,750 entitled VENTILATION MASK WITH INTEGRATED PILOTED EXHALATION VALVE AND METHOD OF VENTILATING A PATIENT USING THE SAME filed Jul. 28, 2011, the disclosures of which are incorporated herein by reference.

STATEMENT RE: FEDERALLY SPONSORED RESEARCH/DEVELOPMENT

Not Applicable

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to systems and methods for controlling delivery of a pressurized flow of breathable gas to a patient and, more particularly, to a ventilation mask such as a full face mask, nasal mask, nasal prongs mask or nasal pillows mask for use in critical care ventilation, respiratory insufficiency or OSA (obstructive sleep apnea) with CPAP (Continuous Positive Airway Pressure) therapy and incorporating a piloted exhalation valve inside the mask.

2. Description of the Related Art

As is known in the medical arts, mechanical ventilators comprise medical devices that either perform or supplement breathing for patients. Early ventilators, such as the "iron lung", created negative pressure around the patient's chest to cause a flow of ambient air through the patient's nose and/or mouth into their lungs. However, the vast majority of contemporary ventilators instead use positive pressure to deliver gas to the patient's lungs via a patient circuit between the ventilator and the patient. The patient circuit typically consists of one or two large bore tubes (e.g., from 22 mm ID for adults to 8 mm ID for pediatric) that interface to the ventilator on one end, and a patient mask on the other end. Most often, the patient mask is not provided as part of the ventilator system, and a wide variety of patient masks can be used with any ventilator. The interfaces between the ventilator, patient circuit and patient masks are standardized as generic conical connectors, the size and shape of which are specified by regulatory bodies (e.g., ISO 5356-1 or similar standards).

Current ventilators are designed to support either "vented" or "leak" circuits, or "non-vented" or "non-leak" circuits. In vented circuits, the mask or patient interface is provided with an intentional leak, usually in the form of a plurality of vent openings. Ventilators using this configuration are most typically used for less acute clinical requirements, such as the treatment of obstructive sleep apnea or respiratory insufficiency. In non-vented circuits, the patient interface is usually not provided with vent openings. Non-vented circuits can have single limb or dual limb patient circuits, and an exhalation valve. Ventilators using non-vented patient circuits are most typically used for critical care applications.

Vented patient circuits are used only to carry gas flow from the ventilator to the patient and patient mask, and require a patient mask with vent openings. When utilizing vented circuits, the patient inspires fresh gas from the patient circuit, and expires CO2-enriched gas, which is purged from the system through the vent openings in the mask. This constant purging of flow through vent openings in the mask when using single-limb circuits provides several disadvantages: 1) it requires the ventilator to provide significantly more flow than the patient requires, adding cost/complexity to the ventilator and requiring larger tubing; 2) the constant flow through the vent openings creates and conducts noise, which has proven to be a significant detriment to patients with sleep apnea that are trying to sleep while wearing the mask; 3) the additional flow coming into proximity of the patient's nose and then exiting the system often causes dryness in the patient, which often drives the need for adding humidification to the system; and 4) patient-expired CO2 flows partially out of the vent holes in the mask and partially into the patient circuit tubing, requiring a minimum flow through the tubing at all times in order to flush the CO2 and minimize the rebreathing of exhaled CO2. To address the problem of undesirable flow of patient-expired CO2 back into the patient circuit tubing, currently known CPAP systems typically have a minimum-required pressure of 4 cm H2O whenever the patient is wearing the mask, which often produces significant discomfort, claustrophobia and/or feeling of suffocation to early CPAP users and leads to a high (approximately 50%) non-compliance rate with CPAP therapy.

When utilizing non-vented dual limb circuits, the patient inspires fresh gas from one limb (the "inspiratory limb") of the patient circuit and expires CO2-enriched gas from the second limb (the "expiratory limb") of the patient circuit. Both limbs of the dual limb patient circuit are connected together in a "Y" proximal to the patient to allow a single conical connection to the patient mask. When utilizing non-vented single limb circuits, an expiratory valve is placed along the circuit, usually proximal to the patient. During the inhalation phase, the exhalation valve is closed to the ambient and the patient inspires fresh gas from the single limb of the patient circuit. During the exhalation phase, the patient expires CO2-enriched gas from the exhalation valve that is open to ambient. The single limb and exhalation valve are usually connected to each other and to the patient mask with conical connections.

In the patient circuits described above, the ventilator pressurizes the gas to be delivered to the patient inside the ventilator to the intended patient pressure, and then delivers that pressure to the patient through the patient circuit. Very small pressure drops develop through the patient circuit, typically around 1 cm H2O, due to gas flow though the small amount of resistance created by the tubing. Some ventilators compensate for this small pressure drop either by mathematical algorithms, or by sensing the tubing pressure more proximal to the patient.

Ventilators that utilize a dual limb patient circuit typically include an exhalation valve at the end of the expiratory limb proximal to the ventilator, while ventilators that utilize a single limb, non-vented patient circuit typically include an exhalation valve at the end of the single limb proximal to the patient as indicated above. Exhalation valves can have fixed or adjustable PEEP (positive expiratory end pressure), typically in single limb configurations, or can be controlled by the ventilator. The ventilator controls the exhalation valve, closes it during inspiration, and opens it during exhalation. Less sophisticated ventilators have binary control of the exhalation valve, in that they can control it to be either open or closed.

More sophisticated ventilators are able to control the exhalation valve in an analog fashion, allowing them to control the pressure within the patient circuit by incrementally opening or closing the valve. Valves that support this incremental control are referred to as active exhalation valves. In existing ventilation systems, active exhalation valves are most typically implemented physically within the ventilator, and the remaining few ventilation systems with active exhalation valves locate the active exhalation valve within the patient circuit proximal to the patient. Active exhalation valves inside ventilators are typically actuated via an electromagnetic coil in the valve, whereas active exhalation valves in the patient circuit are typically pneumatically piloted from the ventilator through a separate pressure source such a secondary blower, or through a proportional valve modulating the pressure delivered by the main pressure source.

BRIEF SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided a mask (e.g., a nasal pillows mask) for achieving positive pressure mechanical ventilation (inclusive of CPAP, ventilatory support, critical care ventilation, emergency applications), and a method for a operating a ventilation system including such mask. The mask preferably includes a pressure sensing modality proximal to the patient connection. Such pressure sensing modality may be a pneumatic port with tubing that allows transmission of the patient pressure back to the ventilator for measurement, or may include a transducer within the mask. The pressure sensing port is used in the system to allow pressure sensing for achieving and/or monitoring the therapeutic pressures. Alternately or additionally, the mask may include a flow sensing modality located therewithin for achieving and/or monitoring the therapeutic flows.

The mask of the present invention also includes a piloted exhalation valve that is used to achieve the target pressures/flows to the patient. In the preferred embodiment, the pilot for the valve is pneumatic and driven from the gas supply tubing from the ventilator. The pilot can also be a preset pressure derived in the mask, a separate pneumatic line from the ventilator, or an electro-mechanical control. In accordance with the present invention, the valve is preferably implemented with a diaphragm.

One of the primary benefits attendant to including the valve inside the mask is that it provides a path for patient-expired CO2 to exit the system without the need for a dual-limb patient circuit, and without the disadvantages associated with a single-limb patient circuit, such as high functional dead space. For instance, in applications treating patients with sleep apnea, having the valve inside the mask allows patients to wear the mask while the treatment pressure is turned off without risk of re-breathing excessive CO2.

Another benefit for having the valve inside the mask is that it allows for a significant reduction in the required flow generated by the ventilator for ventilating the patient since a continuous vented flow for CO2 washout is not required. Lower flow in turn allows for the tubing size to be significantly smaller (e.g., 2-9 mm ID) compared to conventional ventilators (22 mm ID for adults; 8 mm ID for pediatric). However, this configuration requires higher pressures than the patient's therapeutic pressure to be delivered by the ventilator. In this regard, pressure from the ventilator is significantly higher than the patient's therapeutic pressure, though the total pneumatic power delivered is still smaller than that delivered by a low pressure, high flow ventilator used in conjunction with a vented patient circuit and interface. One obvious benefit of smaller tubing is that it provides less bulk for patient and/or caregivers to manage. For today's smallest ventilators, the bulk of the tubing is as significant as the bulk of the ventilator. Another benefit of the smaller tubing is that is allows for more convenient ways of affixing the mask to the patient. For instance, the tubing can go around the patient's ears to hold the mask to the face, instead of requiring straps (typically called "headgear") to affix the mask to the face. Along these lines, the discomfort, complication, and non-discrete look of the headgear is another significant factor leading to the high non-compliance rate for CPAP therapy. Another benefit to the smaller tubing is that the mask can become smaller because it does not need to interface with the large tubing. Indeed, large masks are another significant factor leading to the high non-compliance rate for CPAP therapy since, in addition to being non-discrete, they often cause claustrophobia. Yet another benefit is that smaller tubing more conveniently routed substantially reduces what is typically referred to as "tube drag" which is the force that the tube applies to the mask, displacing it from the patient's face. This force has to be counterbalanced by headgear tension, and the mask movements must be mitigated with cushion designs that have great compliance. The reduction in tube drag in accordance with the present invention allows for minimal headgear design (virtually none), reduced headgear tension for better patient comfort, and reduced cushion compliance that results in a smaller, more discrete cushion.

The mask of the present invention may further include a heat and moisture exchanger (HME) which is integrated therein. The HME can fully or at least partially replace a humidifier (cold or heated pass-over; active or passive) which may otherwise be included in the ventilation system employing the use of the mask. The HME is positioned within the mask so as to be able to intercept the flow delivered from a flow generator to the patient in order to humidify it, and further to intercept the exhaled flow of the patient in order to capture humidity and heat for the next breath. The HME can also be used as a structural member of the mask, adding a cushioning effect and simplifying the design of the cushion thereof.

The present invention is best understood by reference to the following detailed description when read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

These, as well as other features of the present invention, will become more apparent upon reference to the drawings wherein:

FIG. **1** is top perspective view of a nasal pillows mask constructed in accordance with one embodiment of the present invention and including an integrated diaphragm-based piloted exhalation valve;

FIG. **2** is an exploded view of the nasal pillows mask shown in FIG. **1**;

FIG. **3** is a partial cross-sectional view of the nasal pillows mask shown in FIG. **1** taken along lines **3-3** thereof, and depicting the valve pilot lumen extending through the cushion of the mask;

FIG. **4** is a partial cross-sectional view of the nasal pillows mask shown in FIG. **1** taken along lines **4-4** thereof, and depicting the pressure sensing lumen extending through the cushion of the mask;

FIG. **5** is a cross-sectional view of the nasal pillows mask shown in FIG. **1** taken along lines **5-5** thereof;

FIG. **6** is a top perspective view of cushion of the nasal pillows mask shown in FIG. **1**;

FIG. **7** is a top perspective view of exhalation valve of the nasal pillows mask shown in FIG. **1**;

FIG. **8** is a bottom perspective view of exhalation valve shown in FIG. **7**;

FIG. **9** is a cross-sectional view of exhalation valve shown in FIGS. **7** and **8**;

FIG. **10** is a cross-sectional view similar to FIG. **5**, but depicting a variant of the nasal pillows mask shown in FIG. **1** wherein an HME is integrated into the cushion thereof;

FIGS. **11**A, **11**B and **11**C are a series of graphs which provide visual representations corresponding to exemplary performance characteristics of the exhalation valve subassembly of any nasal pillows mask constructed in accordance with the present invention;

FIG. **12** is a schematic representation of an exemplary ventilation system wherein a tri-lumen tube is used to facilitate the operative interface between any nasal pillows mask constructed in accordance with the present invention a flow generating device;

FIG. **13** is a schematic representation of an exemplary ventilation system wherein a bi-lumen tube is used to facilitate the operative interface between any nasal pillows mask constructed in accordance with the present invention and a flow generating device;

FIG. **14** is a side-elevational view of any nasal pillows mask constructed in accordance with the present invention as cooperatively engagement in an exemplary manner to a patient through the use of a headgear assembly;

FIG. **15** is top perspective view of a nasal pillows mask constructed in accordance with another embodiment of the present invention and including an integrated diaphragm-based piloted exhalation valve;

FIG. **16** is an exploded view of the nasal pillows mask shown in FIG. **15**;

FIG. **17** is a partial cross-sectional view of the nasal pillows mask shown in FIG. **15** taken along lines **17-17** thereof, and depicting the valve pilot lumen extending through the cushion of the mask;

FIG. **18** is a partial cross-sectional view of the nasal pillows mask shown in FIG. **15** taken along lines **18-18** thereof, and depicting the pressure sensing lumen extending through the cushion of the mask;

FIG. **19** is a cross-sectional view of the nasal pillows mask shown in FIG. **15** taken along lines **19-19** thereof;

FIG. **20** is a top perspective view of cushion of the nasal pillows mask shown in FIG. **15**;

FIG. **21** is a front elevational view of the exhalation valve subassembly for the nasal pillows mask shown in FIG. **15**;

FIG. **22** is a front exploded view of the exhalation valve subassembly shown in FIG. **21**, depicting the exhalation valve and the shield plate thereof;

FIG. **23** is a rear exploded view of the exhalation valve subassembly shown in FIG. **21**, depicting the exhalation valve and the shield plate thereof;

FIG. **24** is a cross-sectional view of the exhalation valve subassembly shown in FIG. **21** taken along lines **24-24** thereof;

FIG. **25** is a cross-sectional view of the exhalation valve subassembly shown in FIG. **21** taken along lines **25-25** thereof;

FIG. **26** is a an exploded view of the nasal pillows mask shown in FIG. **15** in a partially assembled state prior to the attachment of the frame member to the cushion, and depicting the separation of the strike plate of the exhalation valve subassembly from the exhalation valve thereof which is positioned within the cushion;

FIG. **27** is a cross-sectional view similar to FIG. **19**, but depicting a variant of the nasal pillows mask shown in FIG. **15** wherein an HME is integrated into the cushion thereof; and

FIG. **28** is a cross-sectional view similar to FIGS. **17** and **18**, but depicting a variant of the nasal pillows mask shown in FIG. **15** wherein an HME is integrated into the cushion thereof.

Common reference numerals are used throughout the drawings and detailed description to indicate like elements.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings wherein the showings are for purposes of illustrating various embodiments of the present invention only, and not for purposes of limiting the same, FIGS. **1-4** depict a ventilation mask **10** (e.g., a nasal pillows mask) constructed in accordance with the present invention. Though the mask **10** is depicted as a nasal pillows mask, those skilled in the art will recognize that other ventilation masks are contemplated herein, such as nasal prongs masks, nasal masks, fill face masks and oronasal masks. As such, for purposes of this application, the term mask and/or ventilation mask is intended to encompass all such mask structures. The mask **10** includes an integrated, diaphragm-implemented, piloted exhalation valve **12**, the structural and functional attributes of which will be described in more detail below.

As shown in FIGS. **1-5**, the mask **10** comprises a housing or cushion **14**. The cushion **14**, which is preferably fabricated from a silicone elastomer having a Shore A hardness in the range of from about 20 to 60 and preferably about 40, is formed as a single, unitary component, and is shown individually in FIG. **6**. The cushion **14** includes a main body portion **16** which defines a first outer end surface **18** and an opposed second outer end surface **20**. The main body portion **16** further defines an interior fluid chamber **22** which is of a prescribed volume. In addition to the main body portion **16**, the cushion **14** includes an identically configured pair of hollow pillow portions **24** which protrude from the main body portion **16** in a common direction and in a prescribed spatial relationship relative to each other. More particularly, in the cushion **14**, the spacing between the pillow portions **24** is selected to facilitate the general alignment thereof with the nostrils of an adult patient when the mask **10** is worn by such patient. As seen in FIGS. **3** and **4**, each of the pillow portions **24** fluidly communicates with the fluid chamber **22**.

As shown in FIG. **2**, the main body portion **16** of the cushion **14** includes an enlarged, circularly configured valve opening **26** which is in direct fluid communication with the fluid chamber **22**. The valve opening **26** is positioned in generally opposed relation to the pillow portions **24** of the cushion **14**, and is circumscribed by an annular valve seat **27** also defined by the main body portion **16**. As also shown in FIG. **2**, the main body portion **16** further defines opposed first and second inner end surfaces **28**, **30** which protrude outwardly from the periphery of the valve opening **26**, and are diametrically opposed relative thereto so as to be spaced by an interval of approximately 180°. The valve opening **26**, valve seat **27**, and first and second inner end surfaces **28**, **30** are adapted to accommodate the exhalation valve **12** of the mask **10** in a manner which will be described in more detail below.

As shown FIGS. **3-6**, the main body portion **16** of the cushion **14** further defines first and second gas delivery lumens **32**, **34** which extend from respective ones of the first and second outer end surfaces **18**, **20** into fluid communication with the fluid chamber **22**. Additionally, a pressure sensing lumen **36** defined by the main body portion extends from

the first outer end surface **18** into fluid communication with the fluid chamber **22**. The main body portion **16** further defines a valve pilot lumen **38** which extends between the second outer end surface **20** and the second inner end surface **30**. The use of the first and second gas delivery lumens **32**, **34**, the pressure sensing lumen **36**, and the valve pilot lumen **38** will also be discussed in more detail below. Those of ordinary skill in the art will recognize that the gas delivery lumens **32**, **34**, may be substituted with a single gas delivery lumen and/or positioned within the cushion **14** in orientations other than those depicted in FIG. **6**. For example, the gas delivery lumen(s) of the cushion **14** may be positioned frontally, pointing upwardly, pointing downwardly, etc. rather than extending laterally as shown in FIG. **6**.

Referring now to FIGS. **2-5** and **7-9**, the exhalation valve **12** of the mask **10** is made of three (3) parts or components, and more particularly a seat member **40**, a cap member **42**, and a diaphragm **44** which is operatively captured between the seat and cap members **40**, **42**. The seat and cap members **40**, **42** are each preferably fabricated from a plastic material, with the diaphragm **44** preferably being fabricated from an elastomer having a Shore A hardness in the range of from about 20-40.

As is most easily seen in FIGS. **2**, **7** and **9**, the seat member **40** includes a tubular, generally cylindrical wall portion **46** which defines a distal, annular outer rim **48** and an opposed annular inner seating surface **49**. As shown in FIG. **9**, the diameter of the outer rim **48** exceeds that of the seating surface **49**. Along these lines, the inner surface of the wall portion **46** is not of a uniform inner diameter, but rather is segregated into first and second inner surface sections which are of differing inner diameters, and separated by an annular shoulder **51**. In addition to the wall portion **46**, the seat member **40** includes an annular flange portion **50** which protrudes radially from that end of the wall portion **46** opposite the outer rim **48**. As shown in FIGS. **2** and **7**, the flange portion **50** includes a plurality of exhaust vents **52** which are located about the periphery thereof in a prescribed arrangement and spacing relative to each other. Additionally, as is apparent from FIG. **9**, the seat member **40** is formed such that each of the exhaust vents **52** normally fluidly communicates with the bore or fluid conduit defined by the wall portion **46**.

The cap member **42** of the exhaust valve **12** comprises a circularly configured base portion **54** which defines an inner surface **56** and an opposed outer surface **58**. In addition to the base portion **54**, the cap member **42** includes an annular flange portion **60** which circumvents and protrudes generally perpendicularly relative to the inner surface **56** of the base portion **60**. The flange portion **60** defines a distal annular shoulder **62**. As shown in FIG. **9**, the shoulder **62** and inner surface **56** extend along respective ones of a spaced, generally parallel pair of planes. Further, as shown in FIG. **8**, formed in the outer surface **58** of the base portion **54** is an elongate groove **64** which extends diametrically across the outer surface **58**. The use of the groove **64** will be described in more detail below. The seat and cap members **40**, **42**, when attached to each other in the fully assembled exhalation valve **12**, collectively define an interior valve chamber **59** of the exhalation valve **12**. More particularly, such valve chamber **59** is generally located between the inner surface **56** defined by the base portion **54** of the cap member **42** and the seating surface **49** defined by the wall portion **46** of the seat member **40**.

The diaphragm **44** of the exhalation valve **12**, which resides within the valve chamber **59**, has a circularly configured, central body portion **66**, and a peripheral flange portion **68** which is integrally connected to and circumvents the body portion **66**. The body portion **66** includes an annular lip **72** which circumvents and protrudes upwardly from one side or face thereof. The flange portion **68** includes an arcuately contoured primary region and a distal region which protrudes radially from the primary region. As such, the primary region of the flange portion **68** extends between the distal region thereof and the body portion **66**, and defines a continuous, generally concave channel **70**.

In the exhalation valve **12**, the flange portion **68** of the diaphragm **44** is operatively captured between the flange portions **50**, **60** of the seat and cap members **40**, **42**. More particularly, the annular distal region of the flange portion **68** is compressed (and thus captured) between the shoulder **62** defined by the flange portion **60** of the cap member **42**, and a complimentary annular shoulder **53** which is defined by the flange portion **50** of the seat member **40** proximate the exhaust vents **52**. The orientation of the diaphragm **44** within the valve chamber **59** when captured between the seat and cap members **40**, **42** is such that the channel **70** defined by the arcuately contoured primary region of the flange portion **68** is directed toward or faces the seating surface **49** defined by the wall portion **46** of the seat member **40**.

The diaphragm **44** (and hence the exhalation valve **12**) is selectively moveable between an open position (shown in FIGS. **3-5** and **9**) and a closed position. When in its normal, open position, the diaphragm **44** is in a relaxed, unbiased state. Importantly, in either of its open or closed positions, the diaphragm **44** is not normally seated directly against the inner surface **56** defined by the base portion **54** of the cap member **42**. Rather, a gap is normally maintained between the body portion **66** of the diaphragm **44** and the inner surface **56** of the base portion **54**. The width of such gap when the diaphragm **44** is in its open position is generally equal to the fixed distance separating the inner surface **56** of the base portion **54** from the shoulder **62** of the flange portion **60**. Further, when the diaphragm **44** is in its open position, the body portion **66**, and in particular the lip **72** protruding therefrom, is itself disposed in spaced relation to the seating surface **49** defined by the wall portion **46** of the seat member **40**. As such, when the diaphragm **44** is in its open position, fluid is able to freely pass through the fluid conduit defined by the wall portion **46**, between the seating surface **49** and diaphragm **44**, and through the exhaust vents **52** to ambient air. As shown in FIGS. **3**, **8** and **9**, the flange portion **60** of the cap member **42** is further provided with a pilot port **74** which extends therethrough and, in the fully assembled exhalation valve **12**, fluidly communicates with that portion of the valve chamber **59** disposed between the body portion **66** of the diaphragm **44** and the inner surface **56** of the base portion **54**. The use of the pilot port **74** will also be described in more detail below.

As will be discussed in more detail below, in the exhalation valve **12**, the diaphragm **44** is resiliently deformable from its open position (to which it may be normally biased) to its closed position. An important feature of the present invention is that the diaphragm **44** is normally biased to its open position which provides a failsafe to allow a patient to inhale ambient air through the exhalation valve **12** and exhale ambient air therethrough (via the exhaust vents **52**) during any ventilator malfunction or when the mask **10** is worn without the therapy being delivered by the ventilator. When the diaphragm **44** is moved or actuated to its closed position, the lip **72** of the body portion **66** is firmly seated against the seating surface **49** defined by the wall portion **46** of the seat member **40**. The seating of the lip **72** against the seating surface **49** effectively blocks fluid communication between the fluid conduit defined by the wall portion **46** and the valve chamber **59** (and hence the exhaust vents **52** which fluidly communicate with the valve chamber **59**).

In the mask **10**, the cooperative engagement between the exhalation valve **12** and the cushion **14** is facilitated by the advancement of the wall portion **46** of the seat member **40** into the valve opening **26** defined by the cushion **14**. As best seen in FIG. **5**, such advancement is limited by the ultimate abutment or engagement of a beveled seating surface **76** defined by the flange portion **50** of the seat member **40** against the complimentary valve seat **27** of the cushion **14** circumventing the valve opening **26**. Upon the engagement of the seating surface **76** to the valve seat **27**, the fluid chamber **22** of the cushion **14** fluidly communicates with the fluid conduit defined by the wall portion **46** of the seat member **40**. As will be recognized, if the diaphragm **44** resides in its normal, open position, the fluid chamber **22** is further placed into fluid communication with the valve chamber **59** via the fluid conduit defined by the wall portion **46**, neither end of which is blocked or obstructed by virtue of the gap defined between the lip **72** of the diaphragm **44** and the seating surface **49** of the wall portion **46**.

When the exhalation valve **12** is operatively coupled to the cushion **14**, in addition to the valve seat **27** being seated against the seating surface **76**, the first and second inner end surfaces **28**, **30** of the cushion **14** are seated against respective, diametrically opposed sections of the flange portion **68** defined by the cap member **42**. As best seen in FIGS. **3** and **4**, the orientation of the exhalation valve **12** relative to the cushion **14** is such that the end of the valve pilot lumen **38** extending to the second inner end surface **30** is aligned and fluidly communicates with the pilot port **74** within the flange portion **60**. As such, in the mask **10**, the valve pilot lumen **38** is in continuous, fluid communication with that portion of the valve chamber **59** defined between the inner surface **56** of the base portion **54** and the body portion **66** of the diaphragm **44**.

To assist in maintaining the cooperative engagement between the exhalation valve **12** and the cushion **14**, the mask **10** is further preferably provided with an elongate frame member **78**. The frame member **78** has a generally V-shaped configuration, with a central portion thereof being accommodated by and secured within the complimentary groove **64** formed in the outer surface **58** defined by the base portion **54** of the cap member **42**. As shown in FIGS. **3** and **4**, the opposed end portions of the frame members **78** are cooperatively engaged to respective ones of the first and second outer end surfaces **18**, **20** of the cushion **14**. More particularly, as shown in FIG. **2**, the frame member **78** includes an identically configured pair of first and second connectors **80**, **82** which extend from respective ones of the opposed end portions thereof. An inner portion of the first connector **80** is advanced into and frictionally retained within the first gas delivery lumen **32** of the cushion **14**. Similarly, an inner portion of the second connector **82** is advanced into and frictionally retained within the second gas delivery lumen **34** of the cushion **14**. In addition to the inner portions advanced into respective ones of the first and second gas delivery lumens **32**, **34**, the first and second connectors **80**, **82** of the frame member **78** each further include an outer portion which, as will be described in more detail below, is adapted to be advanced into and frictionally retained within a corresponding lumen of a respective one of a pair of bi-lumen tubes fluidly coupled to the mask **10**.

As shown in FIGS. **3** and **4**, the frame member **78** further includes a tubular, cylindrically configured pressure port **84** which is disposed adjacent the first connector **80**. The pressure port **84** is aligned and fluidly communicates with the pressure sensing lumen **36** of the cushion **14**. Similarly, the frame member **78** is also provided with a tubular, cylindrically configured pilot port **86** which is disposed adjacent the second connector **82**. The pilot port **86** is aligned and fluidly communicates with the valve pilot lumen **38** of the cushion **14**. As will also be discussed in more detail below, the pressure and pilot ports **84**, **86** of the frame member **78** are adapted to be advanced into and frictionally maintained within corresponding lumens of respective ones of the aforementioned pair of bi-lumen tubes which are fluidly connected to the mask **10** within a ventilation system incorporating the same. The receipt of the frame member **78** within the groove **64** of the cap member **42** ensures that the cushion **14**, the exhalation valve **12** and the frame member **78** are properly aligned, and prevents relative movement therebetween. Though not shown, it is contemplated that in one potential variation of the mask **10**, the cushion **14** may be formed so as not to include the valve pilot lumen **38**. Rather, a suitable valve pilot lumen would be formed directly within the frame member **78** so as to extend therein between the pilot port **86** thereof and the pilot port **74** of the exhalation valve **12**.

In the mask **10**, the exhalation valve **12** is piloted, with the movement of the diaphragm **44** to the closed position described above being facilitated by the introduction of positive fluid pressure into the valve chamber **59**. More particularly, it is contemplated that during the inspiratory phase of the breathing cycle of a patient wearing the mask **10**, the valve pilot lumen **38** will be pressurized by a pilot line fluidly coupled to the pilot port **86**, with pilot pressure being introduced into that portion of the valve chamber **59** normally defined between the body portion **66** of the diaphragm **44** and the inner surface **56** defined by the base portion **54** of the cap member **42** via the pilot port **74** extending through the flange portion **60** of the cap member **42**. The fluid pressure level introduced into the aforementioned region of the valve chamber **59** via the pilot port **74** will be sufficient to facilitate the movement of the diaphragm **44** to its closed position described above.

Conversely, during the expiratory phase of the breathing cycle of the patient wearing the mask **10**, it is contemplated that the discontinuation or modulation of the fluid pressure through the valve pilot lumen **38** and hence into the aforementioned region of the valve chamber **59** via the pilot port **74**, coupled with the resiliency of the diaphragm **44** and/or positive pressure applied to the body portion **66** thereof, will facilitate the movement of the diaphragm **44** back to the open position or to a partially open position. In this regard, positive pressure as may be used to facilitate the movement of the diaphragm **44** to its open position may be provided by air which is exhaled from the patient during the expiratory phase of the breathing circuit and is applied to the body portion **66** via the pillows portions **24** of the cushion **14**, the fluid chamber **22**, and the fluid conduit defined by the wall portion of the seat member **40**. As will be recognized, the movement of the diaphragm **44** to the open position allows the air exhaled from the patient to be vented to ambient air after entering the valve chamber **59** via the exhaust vents **52** within the flange portion **50** of the seat member **40** which, as indicated above, fluidly communicate with the valve chamber **59**.

As will be recognized, based on the application of pilot pressure thereto, the diaphragm **44** travels from a fully open position through a partially open position to a fully closed position. In this regard, the diaphragm **44** will be partially open or partially closed during exhalation to maintain desired ventilation therapy. Further, when pilot pressure is discontinued to the diaphragm **44**, it moves to an open position wherein the patient can inhale and exhale through the mask **10** with minimal restriction and with minimal carbon dioxide retention therein. This is an important feature of the present invention which allows a patient to wear the mask **10** without ventilation therapy being applied to the mask **10**, the afore-

mentioned structural and functional features of the mask **10** making it more comfortable to wear, and further allowing it to be worn without carbon dioxide buildup. This feature is highly advantageous for the treatment of obstructive sleep apnea wherein patients complain of discomfort with ventilation therapy due to mask and pressure discomfort. When it is detected that a patient requires sleep apnea therapy, the ventilation therapy can be started (i.e., in an obstructive sleep apnea situation).

To succinctly summarize the foregoing description of the structural and functional features of the mask **10**, during patient inhalation, the valve pilot lumen **38** is pressurized, which causes the diaphragm **44** to close against the seating surface **49**, thus effectively isolating the fluid chamber **22** of the mask **10** from the outside ambient air. The entire flow delivered from a flow generator fluidly coupled to the mask **10** is inhaled by the patient, assuming that unintentional leaks at the interface between the cushion **14** and the patient are discarded. This functionality differs from what typically occurs in a conventional CPAP mask, where venting to ambient air is constantly open, and an intentional leak flow is continuously expelled to ambient air. During patient exhalation, the pilot pressure introduced into the valve pilot lumen **38** is controlled so that the exhaled flow from the patient can be exhausted to ambient air through the exhalation valve **12** in the aforementioned manner. In this regard, the pilot pressure is "servoed" so that the position of the diaphragm **44** relative to the seating surface **49** is modulated, hence modulating the resistance of the exhalation valve **12** to the exhaled flow and effectively ensuring that the pressure in the fluid chamber **22** of the mask **10** is maintained at a prescribed therapeutic level throughout the entire length of the exhalation phase. When the valve pilot lumen **38** is not pressurized, the exhalation valve **12** is in a normally open state, with the diaphragm **44** being spaced from the seating surface **49** in the aforementioned manner, thus allowing the patient to spontaneously breathe in and out with minimal pressure drop (also referred to as back-pressure) in the order of less than about 2 cm H2O at 60 l/min. As a result, the patient can comfortably breathe while wearing the mask **10** and while therapy is not being administered to the patient.

Referring now to FIGS. **11**A, **11**B and **11**C, during use of the mask **10** by a patient, the functionality of the exhalation valve **12** can be characterized with three parameters. These are Pt which is the treatment pressure (i.e., the pressure in the mask **10** used to treat the patient; Pp which is the pilot pressure (i.e., the pressure used to pilot the diaphragm **44** in the exhalation valve **12**); and Qv which is vented flow (i.e., flow that is exhausted from inside the exhalation valve **12** to ambient. These three particular parameters are labeled as Pt, Pp and Qv in FIG. **9**. When the patient is ventilated, Pt is greater than zero, with the functionality of the exhalation valve **12** being described by the family of curves in the first and second quadrants of FIG. **11**A. In this regard, as apparent from FIG. **11**A, for any given Pt, it is evident that by increasing the pilot pressure Pp, the exhalation valve **12** will close and the vented flow will decrease. A decrease in the pilot pressure Pp will facilitate the opening of the valve **12**, thereby increasing vented flow. The vented flow will increase until the diaphragm **44** touches or contacts the inner surface **56** of the base portion **54** of the cap member **42**, and is thus not able to open further. Conversely, when the patient is not ventilated, the inspiratory phase can be described by the third and fourth quadrants. More particularly, Qv is negative and air enters the mask **10** through the valve **12**, with the pressure Pt in the mask **10** being less than or equal to zero. Pilot pressure Pp less than zero is not a configuration normally used during ventilation of the patient, but is depicted for a complete description of the functionality of the valve **12**. The family of curves shown in FIG. **11**A can be described by a parametric equation. Further, the slope and asymptotes of the curves shown in FIG. **11**A can be modified by, for example and not by way of limitation, changing the material used to fabricate the diaphragm **44**, changing the thickness of the diaphragm **44**, changing the area ratio between the pilot side and patient side of the diaphragm **44**, changing the clearance between the diaphragm **44** and the seating surface **49**, and/or changing the geometry of the exhaust vents **52**.

An alternative representation of the functional characteristics of the valve **12** can be described by graphs in which $\Delta P = Pt - Pp$ is shown. For example, the graph of FIG. **11**B shows that for any given Pt, the vented flow can be modulated by changing ΔP. In this regard, ΔP can be interpreted as the physical position of the diaphragm **44**. Since the diaphragm **44** acts like a spring, the equation describing the relative position d of the diaphragm **44** from the seating surface **49** of the seat member **40** is $k \cdot d + Pt \cdot At = Pp \cdot Ap$, where At is the area of the diaphragm **44** exposed to treatment pressure Pt and Ap is the area of the diaphragm **44** exposed to the pilot pressure Pp. A similar, alternative representation is provided in the graph of FIG. **11**C which shows Pt on the x-axis and ΔP as the parameter. In this regard, for any given ΔP, the position d of the diaphragm **44** is determined, with the valve **12** thus being considered as a fixed opening valve. In this scenario Pt can be considered the driving pressure pushing air out of the valve **12**, with FIG. **11**C further illustrating the highly non-linear behavior of the valve **12**.

FIG. **12** provides a schematic representation of an exemplary ventilation system **88** wherein a tri-lumen tube **90** is used to facilitate the fluid communication between the mask **10** and a blower or flow generator **92** of the system **88**. As represented in FIG. **12**, one end of the tri-lumen tube **90** is fluidly connected to the flow generator **92**, with the opposite end thereof being fluidly connected to a Y-connector **94**. The three lumens defined by the tri-lumen tube **90** include a gas delivery lumen, a pressure sensing lumen, and a valve pilot lumen. The gas delivery lumen is provided with an inner diameter or ID in the range of from about 2 mm to 15 mm, and preferably about 4 mm to 10 mm. The pressure sensing and valve pilot lumens of the tri-lumen tube **90** are each preferably provided with an ID in the range of from about 0.5 mm to 2 mm. The outer diameter or OD of the tri-lumen tube **90** is preferably less than 17 mm, with the length thereof in the system **88** being about 2 m. The Y-connector **94** effectively bifurcates the tri-lumen tube **90** into the first and second bi-lumen tubes **96**, **98**, each of which has a length of about 6 inches. The first bi-lumen tube **96** includes a gas delivery lumen having an ID in the same ranges described above in relation to the gas delivery lumen of the tri-lumen tube **90**. The gas delivery lumen of the first bi-lumen tube **96** is fluidly coupled to the outer portion of the first connector **80** of the frame member **78**. The remaining lumen of the first bi-lumen tube **96** is a pressure sensing lumen which has an ID in the same range described above in relation to the pressure sensing lumen of the tri-lumen tube **90**, and is fluidly coupled to the pressure port **84** of the frame member **78**. Similarly, the second bi-lumen tube **98** includes a gas delivery lumen having an ID in the same ranges described above in relation to the gas delivery lumen of the tri-lumen tube **90**. The gas delivery lumen of the second bi-lumen tube **98** is fluidly coupled to the outer portion of the second connector **82** of the frame member **78**. The remaining lumen of the second bi-lumen tube **98** is a valve pilot lumen which has an ID in the same range described

above in relation to the valve pilot lumen of the tri-lumen tube **90**, and is fluidly coupled to the pilot port **86** of the frame member **78**.

In the system **88** shown in FIG. **12**, the pilot pressure is generated at the flow generator **92**. In the prior art, a secondary blower or proportional valve that modulates the pressure from a main blower is used to generate a pressure to drive an expiratory valve. However, in the system **88** shown in FIG. **12**, the outlet pressure of the flow generator **92** is used, with the flow generator **92** further being controlled during patient exhalation in order to have the correct pilot pressure for the exhalation valve **12**. This allows the system **88** to be inexpensive, not needing additional expensive components such as proportional valves or secondary blowers.

FIG. **13** provides a schematic representation of another exemplary ventilation system **100** wherein a bi-lumen tube **102** is used to facilitate the fluid communication between the mask **10** and the blower or flow generator **92** of the system **100**. As represented in FIG. **13**, one end of the bi-lumen tube **102** is fluidly connected to the flow generator **92**, with the opposite end thereof being fluidly connected to the Y-connector **94**. The two lumens defined by the bi-lumen tube **102** include a gas delivery lumen and a pressure sensing lumen. The gas delivery lumen is provided with an inner diameter or ID in the range of from about 2 mm to 10 mm, and preferably about 4 mm to 7 mm. The pressure sensing lumen of the bi-lumen tube **102** is preferably provided with an ID in the range of from about 0.5 mm to 2 mm. The outer diameter or OD of the bi-lumen tube **90** is preferably less than 11 mm, with the length thereof being about 2 m. The Y-connector **94** effectively bifurcates the bi-lumen tube **102** into the first and second bi-lumen tubes **96**, **98**, each of which has a length of about 6 inches. The first bi-lumen tube **96** includes a gas delivery lumen having an ID in the same ranges described above in relation to the gas delivery lumen of the bi-lumen tube **102**. The gas delivery lumen of the first bi-lumen tube **96** is fluidly coupled to the outer portion of the first connector **80** of the frame member **78**. The remaining lumen of the first bi-lumen tube **96** is a pressure sensing lumen which has an ID in the same range described above in relation to the pressure sensing lumen of the bi-lumen tube **102**, and is fluidly coupled to the pressure port **84** of the frame member **78**. Similarly, the second bi-lumen tube **98** includes a gas delivery lumen having an ID in the same ranges described above in relation to the gas delivery lumen of the bi-lumen tube **102**. The gas delivery lumen of the second bi-lumen tube **98** is fluidly coupled to the outer portion of the second connector **82** of the frame member **78**. The remaining lumen of the second bi-lumen tube **98** is a valve pilot lumen which has an ID in the same range described above in relation to the pressure sensing lumen of the bi-lumen tube **102**, and is fluidly coupled to the pilot port **86** of the frame member **78**.

In the system **100** shown in FIG. **13**, the valve pilot lumen **38** is connected to the gas delivery air path at the Y-connector **94**. More particularly, the gas delivery lumen of the bi-lumen tube **102** is transitioned at the Y-connector **94** to the valve pilot lumen of the second bi-lumen tube **98**. As such, the pilot pressure will be proportional to the outlet pressure of the flow generator **92** minus the pressure drop along the bi-lumen tube **102**, which is proportional to delivered flow. This solution is useful when small diameter tubes are used in the system **100**, since such small diameter tubes require higher outlet pressure from the flow generator **92** for the same flow. In this regard, since the pressure at the outlet of the flow generator **92** would be excessive for piloting the exhalation valve **12**, a lower pressure along the circuit within the system **100** is used. In the system **100**, though it is easier to tap in at the Y-connector **94**, anywhere along the tube network is acceptable, depending on the pressure level of the flow generator **92** which is the pressure required by the patient circuit in order to deliver the therapeutic pressure and flow at the patient.

In each of the systems **88**, **100**, it is contemplated that the control of the flow generator **92**, and hence the control of therapeutic pressure delivered to the patient wearing the mask **10**, may be governed by the data gathered from dual pressure sensors which take measurements at the mask **10** and the output of the flow generator **92**. As will be recognized, pressure sensing at the mask **10** is facilitated by the pressure sensing lumen **36** which, as indicated above, is formed within the cushion **14** and fluidly communicates with the fluid chamber **22** thereof. As also previously explained, one of the lumens of the first bi-lumen tube **96** in each of the systems **88**, **100** is coupled to the pressure port **84** (and hence the pressure sensing lumen **36**). As a result, the first bi-lumen tube **96**, Y-connector **94** and one of the tri-lumen or bi-lumen tubes **90**, **102** collectively define a continuous pressure sensing fluid path between the mask **10** and a suitable pressure sensing modality located remotely therefrom. A more detailed discussion regarding the use of the dual pressure sensors to govern the delivery of therapeutic pressure to the patient is found in Applicant's co-pending U.S. application Ser. No. 13/411,257 entitled Dual Pressure Sensor Continuous Positive Airway Pressure (CPAP) Therapy filed Mar. 2, 2012, the entire disclosure of which is incorporated herein by reference.

Referring now to FIG. **10**, there is shown a mask **10***a* which comprises a variant of the mask **10**. The sole distinction between the masks **10**, **10***a* lies in the mask **10***a* including a heat and moisture exchanger or HME **104** which is positioned within the fluid chamber **22** of the cushion **14**. The HME **104** is operative to partially or completely replace a humidifier (cold or heated pass-over; active or passive) which would otherwise be fluidly coupled to the mask **10***a*. This is possible because the average flow through the system envisioned to be used in conjunction with the mask **10***a* is about half of a prior art CPAP mask, due to the absence of any intentional leak in such system.

The HME **104** as a result of its positioning within the fluid chamber **22**, is able to intercept the flow delivered from the flow generator to the patient in order to humidify it, and is further able to capture humidity and heat from exhaled flow for the next breath. The pressure drop created by the HME **104** during exhalation (back-pressure) must be limited, in the order of less than 5 cm H2O at 60 l/min, and preferably lower than 2 cm H2O at 60 l/min. These parameters allow for a low back-pressure when the patient is wearing the mask **10***a* and no therapy is delivered to the patient.

It is contemplated that the HME **104** can be permanently assembled to the cushion **14**, or may alternatively be removable therefrom and thus washable and/or disposable. In this regard, the HME **104**, if removable from within the cushion **14**, could be replaced on a prescribed replacement cycle. Additionally, it is contemplated that the HME **104** can be used as an elastic member that adds elasticity to the cushion **14**. In this regard, part of the elasticity of the cushion **14** may be attributable to its silicone construction, and further be partly attributable to the compression and deflection of the HME **104** inside the cushion **14**.

Referring now to FIGS. **15-19**, there is shown a ventilation mask **110** (e.g., a nasal pillows mask) constructed in accordance with another embodiment of the present invention. Like the mask **10** described above, the mask **110** includes an integrated, diaphragm-implemented, piloted exhalation valve **112**, the structural and functional attributes of which will be described in more detail below.

As shown in FIGS. **15-19**, the mask **110** comprises a housing or cushion **114**. The cushion **114**, which is preferably fabricated from a silicone elastomer having a Shore A hardness in the range of from about 20 to 60 and preferably about 40, is formed as a single, unitary component, and is shown individually in FIG. **20**. The cushion **114** includes a main body portion **116** which defines a first outer end surface **118** and an opposed second outer end surface **120**. The main body portion **116** further defines an interior fluid chamber **122** which is of a prescribed volume. In addition to the main body portion **116**, the cushion **14** includes an identically configured pair of hollow pillow portions **124** which protrude from the main body portion **116** in a common direction and in a prescribed spatial relationship relative to each other. More particularly, in the cushion **114**, the spacing between the pillow portions **124** is selected to facilitate the general alignment thereof with the nostrils of an adult patient when the mask **110** is worn by such patient. Each of the pillow portions **124** fluidly communicates with the fluid chamber **122**.

As shown in FIG. **16**, the main body portion **116** of the cushion **114** includes an enlarged, circularly configured valve opening **126** which is in direct fluid communication with the fluid chamber **122**. The valve opening **126** is positioned in generally opposed relation to the pillow portions **124** of the cushion **114**. The valve opening **126** is adapted to accommodate an exhalation valve subassembly **111** of the mask **110** in a manner which will be described in more detail below.

The main body portion **116** of the cushion **114** further defines first and second gas delivery lumens **132**, **134** which extend from respective ones of the first and second outer end surfaces **118**, **120** into fluid communication with the fluid chamber **122**. Additionally, a pressure sensing lumen **136** defined by the main body portion **116** extends from the first outer end surface **118** into fluid communication with the fluid chamber **122**. The main body portion **116** further defines a valve pilot lumen **138** which extends from the second outer end surface **120** into fluid communication with the fluid chamber. Those of ordinary skill in the art will recognize that the gas delivery lumens **132**, **134** may be substituted with a single gas delivery lumen and/or positioned within the cushion **114** in orientations other than those depicted in FIG. **20**. For example, the gas delivery lumen(s) of the cushion **114** may be positioned frontally, pointing upwardly, pointing downwardly, etc. rather than extending laterally as shown in FIG. **20**. The main body portion **116** of the cushion **114** further includes a mounting aperture **139** formed therein. As seen in FIG. **18**, one end of the mounting aperture **139** communicates with the fluid chamber **122**, with the opposite simply terminating blindly within the main body portion **116**. The use of the first and second gas delivery lumens **132**, **134**, the pressure sensing lumen **136**, the valve pilot lumen **138** and the mounting aperture **139** will be discussed in more detail below.

Referring now to FIGS. **16-19** and **21-26**, the exhalation valve subassembly **111** of the mask **110** comprises the aforementioned exhalation valve **112** in combination with a shield plate **113**. The exhalation valve **112** of the mask **110** is itself made of three (3) parts or components, and more particularly a seat member **140**, a cap member **142**, and a diaphragm **144** which is operatively captured between the seat and cap members **140**, **142**. The seat and cap members **140**, **142** are each preferably fabricated from a plastic material, with the diaphragm **144** preferably being fabricated from an elastomer having a Shore A hardness in the range of from about 20-40.

The seat member **140** includes a tubular, generally cylindrical wall portion **146** which defines a distal, annular outer rim **148** and an opposed annular inner seating surface **149**. The wall portion further defines an outlet conduit **147** which extends between the outer rim **148** and seating surface **149**. In addition to the wall portion **146**, the seat member **140** includes an annular flange portion **150** which is integrally connected to the wall portion **146** by a series of spoke portions **151**. The spoke portions **151** extend to locations on the wall portion **146** proximate the seating surface **149**, with the flange portion **150** being positioned radially outward relative to the wall portion **146**. In the seat member **140**, the wall, flange and spoke portions **146**, **150**, **151** collectively define a plurality of exhaust vents **152** which are located about the periphery of the wall portion **146** in a prescribed arrangement and spacing relative to each other. The seat member **140** is formed such that each of the exhaust vents **152** normally fluidly communicates with the outlet conduit **147** defined by the wall portion **146**.

The cap member **142** of the exhalation valve **112** comprises a circularly configured base portion **154** which defines an inner surface **156**. In addition to the base portion **154**, the cap member **142** includes an annular flange portion **160** which circumvents and protrudes generally perpendicularly relative to the inner surface **156** of the base portion **154**. The cap member **142** further includes an identically configured pair of tube portions **162** which are integrally connected to the flange portion **160** in diametrically opposed relation to each other (i.e., approximately 180° apart). Each of the tube portions defines a lumen **164** extending therethrough and is used for reasons which will be discussed in more detail below. The seat and cap members **140**, **142**, when attached to each other in the fully assembled exhalation valve **112**, collectively define an interior valve chamber of the exhalation valve **112**, such valve chamber generally being located between the inner surface **156** defined by the base portion **154** of the cap member **142** and the seating surface **149** defined by the wall portion **146** of the seat member **140**.

The diaphragm **144** of the exhalation valve **112**, which resides within the valve chamber, has a circularly configured, central body portion **166**, and a peripheral flange portion **168** which is integrally connected to and circumvents the body portion **166**. The flange portion **168** includes an arcuately contoured primary region and a distal region which protrudes radially from the primary region. As such, the primary region of the flange portion **168** extends between the distal region thereof and the body portion **166**, and defines a continuous, generally concave channel **170**. The body portion **166** of the diaphragm **144** may optionally be perforated, i.e., be provided with an array of small apertures which extend therethrough.

In the exhalation valve **112**, the flange portion **168** of the diaphragm **144** is operatively captured between complementary engagement surfaces defined by the flange portions **150**, **160** of the seat and cap members **140**, **142**. More particularly, the annular distal region of the flange portion **168** is compressed (and thus captured) between an annular shoulder defined by the flange portion **160** of the cap member **142**, and a complimentary annular shoulder which is defined by the flange portion **150** of the seat member **140** proximate the exhaust vents **152**. The orientation of the diaphragm **144** within the valve chamber when captured between the seat and cap members **140**, **142** is such that the channel **170** defined by the arcuately contoured primary region of the flange portion **168** is directed toward or faces the seating surface **149** defined by the wall portion **146** of the seat member **140**.

The capture of the diaphragm **144** between the seat and cap members **140**, **142** in the aforementioned manner results in the diaphragm **144** effectively segregating the valve chamber collectively defined by the seat and cap members **140**, **142**

into a pilot section **172** and an exhaust section **174**. The pilot section **172** of the valve chamber is located between the diaphragm **144** and the inner surface **156** of the base portion **154** of the cap member **142**. The exhaust section **174** of the valve chamber is located between the diaphragm **144** and both the exhaust vents **152** and the seating surface **149** of the wall portion **146** of the seat member **140**. In this regard, the outlet conduit **147** defined by the wall portion **146** fluidly communicates with the exhaust section **174** of the valve chamber. In addition, the lumens **164** of the tube portions **162** of the cap member **142** each fluidly communicate with the pilot section **172** of the valve chamber.

The diaphragm **144** (and hence the exhalation valve **112**) is selectively moveable between an open position (shown in FIGS. **17-19** and **24-25**) and a closed position. When in its normal, open position, the diaphragm **144** is in a relaxed, unbiased state. Importantly, in either of its open or closed positions, the diaphragm **144** is not normally seated directly against the inner surface **156** defined by the base portion **154** of the cap member **142**. Rather, a gap is normally maintained between the body portion **166** of the diaphragm **144** and the inner surface **156** of the base portion **154**. The width of such gap when the diaphragm **144** is in its open position is generally equal to the fixed distance separating the inner surface **156** of the base portion **154** from the shoulder of the flange portion **160** which engages the distal region of the flange portion **168** of the diaphragm **144**. Further, when the diaphragm **144** is in its open position, the body portion **166** is itself disposed in spaced relation to the seating surface **149** defined by the wall portion **146** of the seat member **140**. As such, when the diaphragm **144** is in its open position, fluid is able to freely pass through the through the exhaust vents **152**, between the seating surface **149** and diaphragm **144**, and through the outlet conduit **147** defined by the wall portion **146** to ambient air.

In the exhalation valve **112**, the diaphragm **144** is resiliently deformable from its open position (to which it may be normally biased) to its closed position. An important feature of the present invention is that the diaphragm **144** is normally biased to its open position which provides a failsafe to allow a patient to inhale ambient air through the exhalation valve **112** and exhale ambient air therethrough (via the exhaust vents **52**) during any ventilator malfunction or when the mask **110** is worn without the therapy being delivered by the ventilator. When the diaphragm **144** is moved or actuated to its closed position, the periphery of the body portion **166** is firmly seated against the seating surface **149** defined by the wall portion **146** of the seat member **140**. The seating of the body portion **166** of the diaphragm **144** against the seating surface **149** effectively blocks fluid communication between the outlet conduit **147** defined by the wall portion **146** and the exhaust section **174** of the valve chamber (and hence the exhaust vents **152** which fluidly communicate with the exhaust section **174**).

In the mask **110**, the cooperative engagement between the exhalation valve **112** and the cushion **114** is facilitated by the advancement of the cap member **142** into the valve opening **126** defined by the cushion **114**. Subsequent to such advancement, one of the two tube portions **162** of the cap member **142** is partially advanced into and frictionally retained within the pilot lumen **138** of the cushion **114** in the manner shown in FIG. **17**. As is apparent from FIG. **17**, the advancement of one tube portion **162** of the cap member **142** into the pilot lumen **138** facilitates the placement of the pilot lumen **138** into fluid communication with the pilot section **172** of the valve chamber via the lumen **164** of the corresponding tube portion **162**. The remaining tube portion **162** of the cap member **142** (i.e., that tube portion **162** not advanced into the pilot lumen **138**) is advanced into and frictionally retained within the above-described mounting aperture **139** in the manner shown in FIG. **18**. Importantly, the resilient construction of the cushion **114**, and in particular the main body **116** thereof, allows for the cushion **114** to be bent, twisted or otherwise manipulated as is needed to facilitate the advancement of the tube portions **162** of the cap member **142** into respective ones of the pilot lumen **138** and mounting aperture **139** in the aforementioned manner. The advancement of the tube portions **162** into respective ones of the pilot lumen **138** and mounting aperture **139** causes the exhalation valve **112** to assume a position within the fluid chamber **122** of the cushion **114** as is best shown in FIG. **26**. In this regard, the majority of the exhalation valve **112** resides within the fluid chamber **122**, with the exception of a small distal section of the wall portion **148** of the seat member **140** which protrudes from the valve opening **126** of the cushion **114**.

Due to the positioning of the majority of the exhalation valve **114** within the fluid chamber **122**, the exhaust section **174** of the valve chamber is placed into direct fluid communication with the fluid chamber **122** via the exhaust vents **152**. Thus, irrespective of whether the diaphragm **144** of the exhalation valve **112** is in its open or closed positions, the pilot lumen **138** of the cushion **114** is maintained in a constant state of fluid communication with the pilot section **172** of the valve chamber. Additionally, irrespective of whether the diaphragm **144** is in its open or closed positions, the fluid chamber **122** is maintained in a constant state of fluid communication with the exhaust section **174** of the valve chamber via the exhaust vents **152**. When the diaphragm **144** is in its open position, the fluid chamber **122** is further placed into fluid communication with both the outlet conduit **147** (and hence ambient air) via the open flow path defined between the body portion **166** of the diaphragm **144** and the seating surface **149** of the wall portion **146** of the seat member **140**. However, when the diaphragm **144** is moved to its closed position, the fluid communication between the fluid chamber **122** and outlet conduit **147** is effectively blocked by the sealed engagement of the body portion **166** of the diaphragm **144** against the seating surface **149** of the wall portion **146**.

As indicated above, in addition to the exhalation valve **112**, the exhalation valve subassembly **111** includes the shield plate **113**. The shield plate **113** has a generally oval, slightly arcuate profile, and includes a circularly configured opening **175** within the approximate center thereof. Additionally, formed within the peripheral side surface of the shield plate **113** is an elongate groove or channel **176**. In the mask **110**, the shield plate **113** is adapted to be advanced into the valve opening **126** subsequent to the cooperative engagement of the exhalation valve **112** to the cushion **114** in the aforementioned manner. More particularly, the advancement of the shield plate **113** into the valve opening **126** is facilitated in a manner wherein the wall portion **146** of the seat member **140** is advanced into and through the opening **175** of the shield plate **113**. In this regard, the wall portion **146** and the opening **175** have complimentary configurations, with the diameter of the opening **175** only slightly exceeding that of the outer diameter of the wall portion **148**.

Subsequent to the advancement of the wall portion **148** into the opening **175**, that peripheral edge or lip of the main body **116** of the cushion **114** defining the valve opening **126** is advanced into and firmly seated within the complimentary channel **176** formed in the peripheral side surface of the shield plate **113**. The receipt of such edge or lip of the cushion **114** into the channel **176** maintains the shield plate **113** in firm, frictional engagement to the cushion **114**. As is seen in FIGS.

17 and 18, the spatial relationship between the exhalation valve 112 and shield plate 113 when each is cooperatively engaged to the cushion 114 in the aforementioned manner is such that the distal section of the wall portion 146 which defines the outer rim 148 thereof protrudes slightly from the exterior surface of the shield plate 113.

As will be recognized, the shield plate 113, when cooperatively engaged to the cushion 114, effectively encloses that portion of the fluid chamber 122 which would otherwise be directly accessible via the valve opening 126. Importantly, by virtue of the attachment of the shield plate 113 to the main body 116 of the cushion 114, virtually the entirety of the exhalation valve 112 is completely enclosed or contained within the fluid chamber 122 of the cushion 114. As indicated above, only a small distal section of the wall portion 146 of the seat member 140 protrudes from the shield plate 113, and in particular the opening 175 defined thereby. As a result, the exhaust vents 152 which facilitate the fluid communication between the fluid chamber 122 and the exhaust section 174 of the valve chamber, and between the fluid chamber 122 and the outlet conduit 147 (and hence ambient air) when the diaphragm 144 is in the open position, are effectively enclosed within the fluid chamber 122 as provides noise attenuation advantages which will be discussed in more detail below.

To assist in maintaining the cooperative engagement between the exhalation valve subassembly 111 and the cushion 114, the mask 110 is further preferably provided with an elongate reinforcement frame member 178 which is attached to the cushion 114. The frame member 178 has a generally U-shaped configuration, with a central portion thereof including a circularly configured opening 179 formed therein which is adapted to accommodate that aforementioned distal section of the wall portion 146 of the seat member 140 which protrudes from the shield plate 113. In this regard, the diameter of the opening 179 is sized so as to only slightly exceed the outer diameter of the wall portion 146. As seen in FIG. 15, the thickness of the central portion of the frame member 178 is such that when attached to cushion 114 subsequent to the advancement of the wall portion 146 into the complementary opening 179, the outer rim 148 defined by the wall portion 146 is substantially flush or continuous with the exterior surface of the frame member 178.

As shown in FIGS. 17 and 18, the opposed end portions of the frame member 178 are cooperatively engaged to respective ones of the first and second outer end surfaces 118, 120 of the cushion 114. More particularly, the frame member 178 includes an identically configured pair of first and second connectors 180, 182 which are formed on respective ones of the opposed end portions thereof. An inner portion of the first connector 180 is advanced into and frictionally retained within the first gas delivery lumen 132 of the cushion 114. Similarly, an inner portion of the second connector 182 is advanced into and frictionally retained within the second gas delivery lumen 134 of the cushion 114. In addition to the inner portions advanced into respective ones of the first and second gas delivery lumens 132, 134, the first and second connectors 180, 182 of the frame member 178 each further include an outer portion which is adapted to be advanced into and frictionally retained within a corresponding lumen of a respective one of a pair of bi-lumen tubes fluidly coupled to the mask 110, in the same manner as described in detail above in relation to the mask 10.

The frame member 178 further includes a tubular, cylindrically configured pressure port 184 which is disposed adjacent the first connector 180. The pressure port 184 is aligned and fluidly communicates with the pressure sensing lumen 136 of the cushion 114. Similarly, the frame member 178 is also provided with a tubular, cylindrically configured pilot port 186 which is disposed adjacent the second connector 182. The pilot port 186 is aligned and fluidly communicates with the valve pilot lumen 138 of the cushion 114. The pressure and pilot ports 184, 186 of the frame member 78 are adapted to be placed into fluid communication with corresponding lumens of respective ones of the aforementioned pair of bi-lumen tubes which are fluidly connected to the mask 110 within a ventilation system incorporating the same, also in the same manner as described in detail above in relation to the mask 10. The receipt of the wall portion 146 of the seat member 140 into the opening 179 of the frame member 178 ensures that the cushion 114, the exhalation valve subassembly 111 and the frame member 178 are properly aligned, and prevents relative movement therebetween.

In the mask 110, the exhalation valve 112 is piloted, with the movement of the diaphragm 144 to the closed position described above being facilitated by the introduction of positive fluid pressure into the pilot section 172 of the valve chamber. More particularly, it is contemplated that during the inspiratory phase of the breathing cycle of a patient wearing the mask 110, the valve pilot lumen 138 will be pressurized by a pilot line fluidly coupled to the pilot port 186, with pilot pressure being introduced into that portion of the pilot section 172 of the valve chamber via the pilot lumen 138 and the lumen 164 of that tube portion 162 of the cap member 142 advanced into the pilot lumen 138. The fluid pressure level introduced into the pilot section 172 of the valve chamber will be sufficient to facilitate the movement of the diaphragm 144 to its closed position described above. When the diaphragm 144 is in its closed position, fluid pressure introduced into the fluid chamber 122 via the gas delivery lumens 136, 138 is prevented from being exhausted to ambient air. In this regard, though such fluid may flow from the fluid chamber 122 into the exhaust section 174 of the valve chamber via the exhaust vents 152, the engagement of the diaphragm 144 to the seating surface 149 defined by the wall portion 146 of the seat member 140 effectively blocks the flow of such fluid into the outlet conduit defined by the wall portion 146 and hence to ambient air.

Conversely, during the expiratory phase of the breathing cycle of the patient wearing the mask 110, it is contemplated that the discontinuation or modulation of the fluid pressure through the valve pilot lumen 138 and hence into the pilot section 172 of the valve chamber, coupled with the resiliency of the diaphragm 144 and/or positive pressure applied to the body portion 166 thereof, will facilitate the movement of the diaphragm 144 back to the open position or to a partially open position. In this regard, positive pressure as may be used to facilitate the movement of the diaphragm 144 to its open position may be provided by air which is exhaled from the patient during the expiratory phase of the breathing circuit and is applied to the body portion 166 of the diaphragm 144 via the pillows portions 124 of the cushion 114, the fluid chamber 122, the exhaust vents 152, and the exhaust section 174 of the valve chamber. As will be recognized, the movement of the diaphragm 144 to the open position allows the air exhaled from the patient into the fluid chamber 122 via the pillow portions 124 to be vented to ambient air after flowing from the fluid chamber 122 into the exhaust section 174 of the valve chamber via the exhaust vents 152, and thereafter flowing from the exhaust section 174 between the diaphragm 144 and seating surface 149 of the wall portion 146 into the outlet conduit 147 also defined by the wall portion 146.

As will be recognized, based on the application of pilot pressure thereto, the diaphragm 144 travels from a fully open position through a partially open position to a fully closed

position. In this regard, the diaphragm **144** will be partially open or partially closed during exhalation to maintain desired ventilation therapy. Further, when pilot pressure is discontinued to the diaphragm **144**, it moves to an open position wherein the patient can inhale and exhale through the mask **110** with minimal restriction and with minimal carbon dioxide retention therein. This is an important feature of the present invention which allows a patient to wear the mask **110** without ventilation therapy being applied to the mask **110**, the aforementioned structural and functional features of the mask **110** making it more comfortable to wear, and further allowing it to be worn without carbon dioxide buildup. This feature is highly advantageous for the treatment of obstructive sleep apnea wherein patients complain of discomfort with ventilation therapy due to mask and pressure discomfort. When it is detected that a patient requires sleep apnea therapy, the ventilation therapy can be started (i.e., in an obstructive sleep apnea situation).

To succinctly summarize the foregoing description of the structural and functional features of the mask **110**, during patient inhalation, the valve pilot lumen **138** is pressurized, which causes the diaphragm **144** to close against the seating surface **149**, thus effectively isolating the fluid chamber **122** of the mask **110** from the outside ambient air. The entire flow delivered from a flow generator fluidly coupled to the mask **110** is inhaled by the patient, assuming that unintentional leaks at the interface between the cushion **114** and the patient are discarded. This functionality differs from what typically occurs in a conventional CPAP mask, where venting to ambient air is constantly open, and an intentional leak flow is continuously expelled to ambient air. During patient exhalation, the pilot pressure introduced into the valve pilot lumen **138** is controlled so that the exhaled flow from the patient can be exhausted to ambient air through the exhalation valve **112** in the aforementioned manner. In this regard, the pilot pressure is "servoed" so that the position of the diaphragm **144** relative to the seating surface **149** is modulated, hence modulating the resistance of the exhalation valve **112** to the exhaled flow and effectively ensuring that the pressure in the fluid chamber **122** of the mask **110** is maintained at a prescribed therapeutic level throughout the entire length of the exhalation phase. When the valve pilot lumen **138** is not pressurized, the exhalation valve **112** is in a normally open state, with the diaphragm **144** being spaced from the seating surface **149** in the aforementioned manner, thus allowing the patient to spontaneously breathe in and out with minimal pressure drop (also referred to as back-pressure) in the order of less than about 2 cm H2O at 60 l/min. As a result, the patient can comfortably breathe while wearing the mask **110** and while therapy is not being administered to the patient. Importantly, the effective containment of the exhaust vents **152** within the fluid chamber **122** substantially mitigates or suppresses the noise generated by the mask **110** attributable to the flow of fluid into the exhaust section **174** of the valve chamber via the exhaust vents **152**.

Those of ordinary skill in the art will recognize that the functionality of the exhalation valve **112** during use of the mask **110** by a patient can be characterized with the same three parameters described above in relation to the mask **10** and shown in FIGS. **11**A, **11**B and **11**C. However, based on the structural features of the exhalation valve **112** in comparison to the exhalation valve **12**, the parameters Pt which is the treatment pressure (i.e., the pressure in the mask **110** used to treat the patient; Pp which is the pilot pressure (i.e., the pressure used to pilot the diaphragm **144** in the exhalation valve **112**); and Qv which is vented flow (i.e., flow that is exhausted from inside the exhalation valve **112** to ambient are labeled in FIG. **18** as Pt, Pp and Qv in the context of the exhalation valve **112**. As such, when the patient is ventilated, Pt is greater than zero, with the functionality of the exhalation valve **112** being described by the family of curves in the first and second quadrants of FIG. **11**A. In this regard, as apparent from FIG. **11**A, for any given Pt, it is evident that by increasing the pilot pressure Pp, the exhalation valve **112** will close and the vented flow will decrease. A decrease in the pilot pressure Pp will facilitate the opening of the exhalation valve **112**, thereby increasing vented flow. The vented flow will increase until the diaphragm **144** touches or contacts the inner surface **156** of the base portion **154** of the cap member **142**, and is thus not able to open further. Conversely, when the patient is not ventilated, the inspiratory phase can be described by the third and fourth quadrants. More particularly, Qv is negative and air enters the mask **110** through the exhalation valve **112**, with the pressure Pt in the mask **110** being less than or equal to zero. Pilot pressure Pp less than zero is not a configuration normally used during ventilation of the patient, but is depicted for a complete description of the functionality of the exhalation valve **112**. The family of curves shown in FIG. **11**A can be described by a parametric equation. Further, the slope and asymptotes of the curves shown in FIG. **11**A can be modified by, for example and not by way of limitation, changing the material used to fabricate the diaphragm **144**, changing the thickness of the diaphragm **144**, changing the area ratio between the side of the diaphragm **144** facing the pilot section **172** and the side facing the exhaust section **174**, changing the clearance between the diaphragm **144** and the seating surface **149**, and/or changing the geometry of the exhaust vents **152**.

As also discussed above in relation to the mask **10**, an alternative representation of the functional characteristics of the valve **112** can be described by graphs in which $\Delta P = Pt - Pp$ is shown. For example, the graph of FIG. **11**B shows that for any given Pt, the vented flow can be modulated by changing ΔP. In this regard, ΔP can be interpreted as the physical position of the diaphragm **144**. Since the diaphragm **144** acts like a spring, the equation describing the relative position d of the diaphragm **144** from the seating surface **149** of the seat member **140** is $k \cdot d + Pt \cdot At = Pp \cdot Ap$, where At is the area of the diaphragm **144** exposed to treatment pressure Pt and Ap is the area of the diaphragm **144** exposed to the pilot pressure Pp. A similar, alternative representation is provided in the graph of FIG. **11**C which shows Pt on the x-axis and ΔP as the parameter. In this regard, for any given ΔP, the position d of the diaphragm **144** is determined, with the exhalation valve **112** thus being considered as a fixed opening valve. In this scenario Pt can be considered the driving pressure pushing air out of the exhalation valve **112**, with FIG. **11**C further illustrating the highly non-linear behavior of the valve **112**.

The mask **110** may also be integrated into each of the above-described ventilation systems **88**, **100** in substitution for the mask **10**. In this regard, as will be recognized by those of ordinary skill in the art, the first and second bi-lumen tubes **96**, **98** of such ventilation systems **88**, **100** would simply be cooperatively engaged to corresponding ones of the first and second connectors **180**, **182**, pressure port **184** and pilot port **186** of the frame member **178** in the same manner described above regarding the engagement to the first and second connectors **80**, **82**, pressure port **84** and pilot port **86** of the frame member **78**.

In the mask **110**, it is contemplated that exhalation vale subassembly **111**, and in particular the exhalation valve **112**, may be detached from the cushion **114** and removed from within the fluid chamber **122** as needed for periodic cleaning or replacement thereof. As will be recognized, such removal

is facilitated by first detaching the shield plate **113** from the cushion **114** by removing the lip of the cushion **114** defining the valve opening **126** from within the channel **176** of the shield plate **113**. Thereafter, the exhalation valve **112** is simply grasped and pulled from within the fluid chamber **122**, the flexibility/resiliency of the cushion **114** allowing for the easy removal of the tube portions **162** of the cap member **142** from within respective ones of the pilot lumen **138** and mounting aperture **139**. The re-attachment of the exhalation valve subassembly **111** to the cushion **114** occurs in the reverse sequence, the exhalation valve **112** being advanced into the fluid chamber **122** and attached to the cushion **114** in the aforementioned manner prior to the attachment of the shield plate **113** to the cushion **114** in the aforementioned manner.

Referring now to FIGS. **27** and **28**, there is shown a mask **110***a* which comprises a variant of the mask **110**. The sole distinction between the masks **110**, **110***a* lies in the mask **110***a* including a heat and moisture exchanger or HME **204** which is positioned within the fluid chamber **122** of the cushion **114**. The HME **204** is operative to partially or completely replace a humidifier (cold or heated pass-over; active or passive) which would otherwise be fluidly coupled to the mask **110***a*. This is possible because the average flow through the system envisioned to be used in conjunction with the mask **110***a* is about half of a prior art CPAP mask, due to the absence of any intentional leak in such system.

The HME **204**, as a result of its positioning within the fluid chamber **122**, is able to interact with the flow delivered from the flow generator to the patient in order to humidify it, and is further able to capture humidity and heat from exhaled flow for the next breath. The pressure drop created by the HME **204** during exhalation (back-pressure) must be limited, in the order of less than 5 cm H2O at 60 l/min, and preferably lower than 2 cm H2O at 60 l/min. These parameters allow for a low back-pressure when the patient is wearing the mask **110***a* and no therapy is delivered to the patient.

It is contemplated that the HME **204** can be permanently assembled to the cushion **114**, or may alternatively be removable therefrom and thus washable and/or disposable. In this regard, the HME **204**, if removable from within the cushion **114**, could be replaced on a prescribed replacement cycle. As will be recognized, the removal of the HME **204** from within the fluid chamber **122** would follow the detachment of the exhalation valve subassembly **111** from the cushion **114** in the manner described above. Similarly, the placement of the HME **204** back into the fluid chamber **122** would precede the reattachment of the exhalation valve subassembly **111** to the cushion **114** in the manner also described above. Additionally, it is contemplated that the HME **204** can be used as an elastic member that adds elasticity to the cushion **114**. In this regard, part of the elasticity of the cushion **114** may be attributable to its silicone construction, and further be partly attributable to the compression and deflection of the HME **204** inside the cushion **114**.

The integration of the exhalation valve **12**, **112** into the cushion **14**, **114** and in accordance with the present invention allows lower average flow compared to prior art CPAP masks. As indicated above, normal masks have a set of apertures called "vents" that create a continuous intentional leak during therapy. This intentional leak or vented flow is used to flush out the exhaled carbon dioxide that in conventional CPAP machines, with a standard ISO taper tube connecting the mask to the flow generator or blower, fills the tubing up almost completely with carbon dioxide during exhalation. The carbon dioxide accumulated in the tubing, if not flushed out through the vent flow, would be inhaled by the patient in the next breath, progressively increasing the carbon dioxide content in the inhaled gas at every breath. The structural/functional features of the exhalation valve **12**, **112**, in conjunction with the use of small inner diameter, high pneumatic resistance tubes in the system in which the mask **10**, **10***a*, **110**, **110***a* is used, ensures that all the exhaled gas goes to ambient. As a result, a vent flow is not needed for flushing any trapped carbon dioxide out of the system. Further, during inspiration the exhalation valve **12**, **112** can close, and the flow generator of the system needs to deliver only the patient flow, without the additional overhead of the intentional leak flow. In turn, the need for lower flow rates allows for the use of smaller tubes that have higher pneumatic resistance, without the need for the use of extremely powerful flow generators. The pneumatic power through the system can be kept comparable to those of traditional CPAP machines, though the pressure delivered by the flow generator will be higher and the flow lower.

The reduced average flow through the system in which the mask **10**, **10***a*, **110**, **110***a* is used means that less humidity will be removed from the system, as well as the patient. Conventional CPAP systems have to reintegrate the humidity vented by the intentional leak using a humidifier, with heated humidifiers being the industry standard. Active humidification introduces additional problems such as rain-out in the system tubing, which in turn requires heated tubes, and thus introducing more complexity and cost into the system. The envisioned system of the present invention, as not having any intentional leak flow, does not need to introduce additional humidity into the system. As indicated above, the HME **104**, **204** can be introduced into the cushion **14**, **114** of the mask **10***a*, **110***a* so that exhaled humidity can be trapped and used to humidify the air for the following breath.

In addition, a big portion of the noise of conventional CPAP systems is noise conducted from the flow generator through the tubing up to the mask and then radiated in the ambient through the vent openings. As previously explained, the system described above is closed to the ambient during inhalation which is the noisiest part of the therapy. The exhaled flow is also lower than the prior art so it can be diffused more efficiently, thus effectively decreasing the average exit speed and minimizing impingement noise of the exhaled flow on bed sheets, pillows, etc.

As also explained above, a patient can breathe spontaneously when the mask **10**, **10***a*, **110**, **100***a* is worn and not connected to the flow generator tubing, or when therapy is not administered. In this regard, there will be little back pressure and virtually no carbon dioxide re-breathing, due to the presence of the exhalation valve **12**, **112** that is normally open and the inner diameters of the tubes integrated into the system. This enables a zero pressure start wherein the patient falls asleep wearing the mask **10**, **10***a*, **110**, **110***a* wherein the flow generator does not deliver any therapy. Prior art systems can only ramp from about 4 m H2O up to therapy pressure. A zero pressure start is more comfortable to patients that do not tolerate pressure.

As seen in FIG. **14**, due to the reduced diameter of the various tubes (i.e., the tri-lumen tube **90** and bi-lumen tubes **96**, **98**, **102**) integrated into the system **88**, **100**, such tubes can be routed around the patient's ears similar to conventional O2 cannulas. More particularly, the tubing can go around the patient's ears to hold the mask **10**, **10***a*, **110**, **110***a* to the patient's face. This removes the "tube drag" problem described above since the tubes will not pull the mask **10**, **10***a* away from the face of the patient when he or she moves. As previously explained, "tube drag" typically decreases mask stability on the patient and increases unintentional leak that annoys the patient. In the prior art, head gear tension is used

to counter balance the tube drag, which leads to comfort issues. The tube routing of the present invention allows for lower head gear tension and a more comfortable therapy, especially for compliant patients that wear the mask **10**, **10***a*, **110**, **110***a* approximately eight hours every night. The reduction in tube drag in accordance with the present invention also allows for minimal headgear design (virtually none), reduced headgear tension for better patient comfort as indicated above, and reduced cushion compliance that results in a smaller, more discrete cushion **14**, **114**. The tube dangling in front of the patient, also commonly referred to as the "elephant trunk" by patients, is a substantial psychological barrier to getting used to therapy. The tube routing shown in FIG. **14**, in addition to making the mask **10**, **10***a*, **110**, **110***a* more stable upon the patient, avoids this barrier as well. Another benefit to the smaller tubing is that the mask **10**, **10***a*, **110**, **110***a* can become smaller because it does not need to interface with large tubing. Indeed, large masks are another significant factor leading to the high non-compliance rate for CPAP therapy since, in addition to being non-discrete, they often cause claustrophobia.

This disclosure provides exemplary embodiments of the present invention. The scope of the present invention is not limited by these exemplary embodiments. Numerous variations, whether explicitly provided for by the specification or implied by the specification, such as variations in structure, dimension, type of material and manufacturing process may be implemented by one of skill in the art in view of this disclosure.

What is claimed is:

1. A ventilation mask, comprising:

a housing sized and configured to be positionable between a patient's nose and mouth in contact with the patient's nose, the housing defining an internal fluid chamber, at least one gas delivery lumen which fluidly communicates with the fluid chamber, and a valve pilot lumen; and

a piloted exhalation valve attached to the housing and at least partially residing within the fluid chamber thereof, the exhalation valve comprising:

a valve housing defining a valve chamber which fluidly communicates with the fluid chamber, the pilot lumen and ambient air; and

a diaphragm disposed within the valve chamber, the diaphragm normally being biased to an open position wherein the fluid chamber fluidly communicates with ambient air via the valve chamber, and a closed position wherein fluid communication between the fluid chamber and ambient air is blocked thereby, the movement of the diaphragm from the open position to the closed position being facilitated by the selective pressurization of at least a portion of the valve chamber via the pilot lumen.

2. The ventilation mask of claim **1** wherein the housing further defines a pressure sensing lumen which fluidly communicates with the fluid chamber.

3. The ventilation mask of claim **1** wherein the housing is a resilient cushion including a spaced pair of hollow pillow portions which each fluidly communicate with the fluid chamber and are adapted to engage respective ones of the nostrils of the patient's nose.

4. The ventilation mask of claim **3** further comprising a heat and moisture exchanger disposed within the fluid chamber between the exhalation valve and the pillow portions of the cushion.

5. The ventilation mask of claim **3** wherein the valve housing comprises:

a seat member; and

a cap member attached to the seat member, the seat and cap members collectively defining the valve chamber;

the diaphragm being captured between the seat and cap members in a manner wherein the diaphragm effectively segregates the valve chamber into a pilot section which fluidly communicates with the pilot lumen and an exhaust section which fluidly communicates with the fluid chamber in ambient air.

6. The ventilation mask of claim **5** wherein the diaphragm and the seat member define complimentary seating surfaces which are sized and configured relative to each other such that the movement of the diaphragm to the closed position facilitates the placement of the seating surfaces into sealed engagement with each other in a manner blocking fluid communication between the fluid chamber and ambient air.

7. The ventilation mask of claim **6** wherein the seat member includes a plurality of vents which are disposed therein and collectively define a fluid conduit between the fluid chamber and the exhaust section of the valve chamber.

8. The ventilation mask of claim **7** wherein the vents of the seat member reside within the fluid chamber of the cushion.

9. The ventilation mask of claim **8** further comprising a shield plate attached to the cushion and partially defining the fluid chamber, the shield plate including an opening therein which is sized and configured to accommodate a portion of the seat member.

10. The ventilation mask of claim **9** further comprising a reinforcement frame member which is attached to the cushion, the frame member spanning the shield plate and including an opening therein which is coaxially aligned with the opening of the shield plate and is size and configured to accommodate a portion of the seat member.

11. A ventilation mask, comprising:

a housing sized and configured to be positionable between a patient's nose and mouth in contact with the patient's nose, the housing defining an internal fluid chamber; and

an exhalation valve attached to the housing and at least partially residing within the fluid chamber thereof, the exhalation valve comprising:

a valve housing defining a valve chamber which fluidly communicates with the fluid chamber via at least one vent and with ambient air via at least one outlet conduit; and

a diaphragm disposed within the valve chamber, the diaphragm being selectively movable between an open position wherein the fluid chamber fluidly communicates with ambient air via the valve chamber, and a closed position wherein fluid communication between the fluid chamber and ambient air is blocked thereby;

the vent of the valve housing residing and being enclosed within the fluid chamber, with the outlet conduit of the valve housing protruding from the fluid chamber.

12. The ventilation mask of claim **11** wherein the housing is a resilient cushion including a spaced pair of hollow pillow portions which each fluidly communicate with the fluid chamber and are adapted to engage respective ones of the nostrils of a patient's nose.

13. The ventilation mask of claim **12** further comprising a heat and moisture exchanger disposed within the fluid chamber between the exhalation valve and the pillow portions of the cushion.

14. The ventilation mask of claim **12** wherein the valve housing comprises:

a seat member defining the vent and the outlet conduit; and

a cap member attached to the seat member, the seat and cap members collectively defining the valve chamber;

the diaphragm being captured between the seat and cap members in a manner wherein the diaphragm effectively segregates the valve chamber into at least two sections, one of which fluidly communicates with the vent and the outlet conduit.

15. The ventilation mask of claim **14** wherein the diaphragm and the seat member define complimentary seating surfaces and are sized and configured relative to each other such that the movement of the diaphragm to the closed position facilitates the placement of the seating surfaces into sealed engagement with each other in a manner blocking fluid communication between the vent and the outlet conduit.

16. The ventilation mask of claim **15** wherein the seat member includes a plurality of vents which collectively define a fluid conduit.

17. The ventilation mask of claim **15** further comprising a shield plate attached to the cushion and partially defining the fluid chamber, the shield plate including an opening therein which is sized and configured to accommodate a portion of the seat member which defines the outlet conduit thereof.

18. The ventilation mask of claim **17** further comprising a reinforcement frame member which is attached to the cushion, the frame member spanning the shield plate and including an opening therein which is coaxially aligned with the opening of the shield plate and is sized and configured to accommodate the portion of the seat member which defines the outlet conduit thereof.

19. A ventilation mask, comprising:

a housing sized and configured to be positionable between a patient's nose and mouth in contact with the patient's nose, the housing defining an internal fluid chamber, at least one gas delivery lumen which fluidly communicates with the fluid chamber, and a valve pilot lumen; and

an exhalation valve at least partially residing within the fluid chamber of the housing, the exhalation valve including:

a valve chamber which fluidly communicates with the fluid chamber, the pilot lumen and ambient air; and

a diaphragm which is disposed within the valve chamber, the diaphragm being movable between an open position wherein the fluid chamber fluidly communicates with ambient air via the valve chamber, and a closed position wherein fluid communication between the fluid chamber and ambient air is blocked thereby;

the movement of the diaphragm from the open position to the closed position being facilitated by the selective pressurization of at least a portion of the valve chamber via the pilot lumen.

20. The ventilation mask of claim **19** wherein the housing further defines a pressure sensing lumen which fluidly communicates with the fluid chamber.

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